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Practical evaluation of GE Healthcare SenoClaire digital breast tomosynthesis system

NHS Breast Screening Programme Equipment Report 1504

January 2016

NHS Cancer Screening Programmes

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This evaluation was performed as a parallel process alongside a clinical trial “The accuracy of GE digital breast tomosynthesis versus supplementary mammographic views for diagnosis of screen-detected soft-tissue breast lesions”.

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Contents

Executive summary

The purpose of this evaluation was to assess the practical performance of the GE Healthcare SenoClaire tomosynthesis system for use within the NHS Breast Screening Programme (NHSBSP), in the assessment of recalled women.

The evaluation was carried out between March and September 2014. The Image Diagnost International (IDI) reporting workstation is also included for its role in the review of tomosynthesis images.

The majority of radiographers found the tomosynthesis system easy to use, and overall the women being assessed did not indicate that the tomosynthesis attachment was uncomfortable. The workflow was a little restricted, due to limited access to alternative equipment during very busy assessment clinics, but not due to the tomosynthesis process itself.

The radiologists were very positive about the feasibility and diagnostic value of tomosynthesis. The visualisation of various lesion types was overall felt to be the same as or better than standard additional views. Radiologists frequently reported added value with tomosynthesis in the assessment of asymmetric densities, when tomosynthesis added confidence to a normal result. This relates to the ability of tomosynthesis to demonstrate the composite nature of an apparent soft tissue density. It thus improves the specificity of the assessment process and reduces the need for unnecessary benign biopsies.

A dose survey was carried out for two-view tomosynthesis images of the breast being assessed. The average mean glandular dose for the 50-60mm breast was 1.50mGy and 1.51mGy for tomosynthesis images in Derby and Nottingham respectively, well within the dose limits for 2D mammography.

1. Introduction

1.1 The evaluation centres

This evaluation was carried out at two centres, the Derby Breast Unit and the Nottingham Breast Institute. Both of these centres meet the relevant national quality standards for breast screening and also meet the criteria for evaluation centres outlined in the NHSBSP Guidance Notes for Equipment Evaluation.[1]

The evaluation took place between March 2014 and September 2014 in conjunction with a twin centre clinical research trial[2] of the GE SenoClaire digital breast tomosynthesis system that was already in progress at the two sites.

The Derby Breast Unit is an NHSBSP unit that invites approximately 31,000 women per year for screening, of whom 25,000 are screened. Approximately 730 assessments are carried out per year. As part of the clinical trial, 162 women were recruited for assessment with the tomosynthesis system.

The Nottingham Breast Institute is an NHSBSP unit that invites approximately 40,000 women per year for screening of whom 30,400 are screened. Approximately 800 assessments are carried out per year. During the clinical trial, it also recruited 162 women for assessment with the tomosynthesis system.

Two patients were diagnosed with non-breast cancer malignancies and were therefore excluded from the trial data analysis. The dataset for this evaluation was obtained from a subset of 61 out of the 322 women who took part in the clinical research trial, which already had ethics approval.

1.2 Equipment evaluated

1.2.1 GE Healthcare SenoClaire

The GE Healthcare SenoClaire digital breast tomosynthesis (DBT) system is an optional module available for use with the GE Essential digital mammography equipment. The SenoClaire is used for the acquisition of tomosynthesis images, for which the dose to the woman is approximately equal to the dose for a standard 2D acquisition of the same view.

The technical evaluation of the GE Essential mammography equipment was published in 2008[3], and a technical evaluation of the profile automatic exposure control software

was published in 2009.[4] The technical evaluation of the GE Healthcare SenoClaire was carried out in 2014.[5]

Figure 1 shows the GE Healthcare SenoClaire system.

Figure 1. GE Healthcare Senographe Essential with SenoClaire tomosynthesis attachment

The SenoClaire tomosynthesis attachment is called a motorised tomosynthesis device (MTD) and is attached in place of the standard 2D Bucky. 2D imaging may be performed either using the standard 2D Bucky or using the MTD in 2D mode. The MTD

can be left permanently in place and used for both 2D and tomosynthesis imaging. It has a 3D light which indicates whether tomosynthesis is enabled or disabled, as shown in Figures 2 and 3. When the light is off, as in Figure 3, the MTD can be used for 2D digital mammography. Its performance differs slightly from that of the standard 2D Bucky, as was detailed in the technical evaluation.[5]

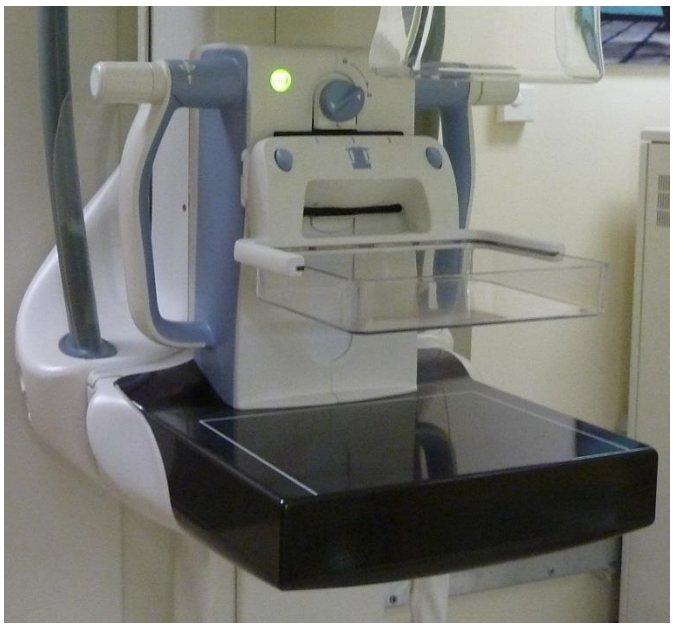

Figure 2. 3D light on shows MTD is enabled

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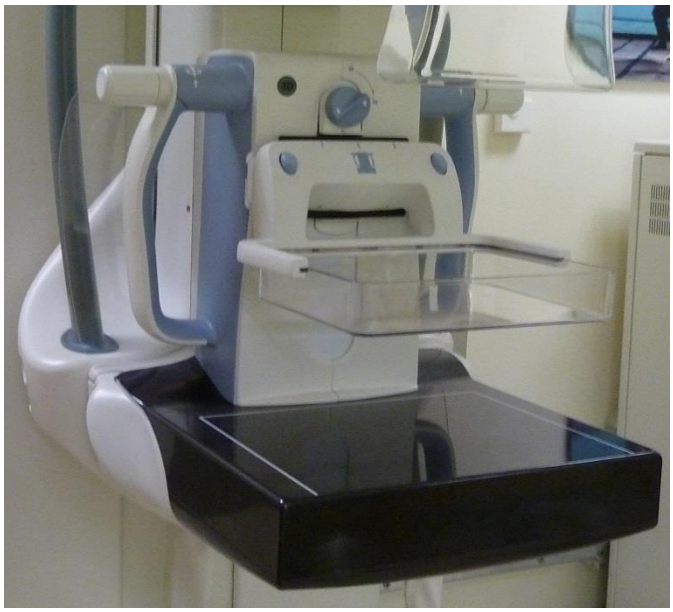

Figure 3. 3D light off shows MTD is disabled

Figure 4 shows the specially designed cart which was provided during the evaluation. It made the attachment and removal of the MTD easy, with minimal handling that required no lifting. It also provided a useful storage platform.

Figure 4. MTD on mobile cart

1.2.2 Accessories

1.2.2.1 Paddles

The MTD has two paddle sizes: a standard 24cm x 31cm paddle and a smaller 19cm x 23cm paddle. An elevated 24cm x 31cm paddle is also available, which allows more

space for positioning breasts of compressed thickness of 45mm or more. The paddles can easily be removed for cleaning.

1.2.2.2 Face shield

A face shield is provided with the equipment. It remains in place during tomosynthesis acquisition and moves along with the angulation of the gantry.

1.2.3 Operation

The operator console is unchanged from that of the GE Senographe Essential, with operators using a password to log into the system. All the radiographers using the SenoClaire tomosynthesis system were already familiar with the Senographe Essential. The only additional feature when using the system in tomosynthesis mode is a dedicated tomosynthesis foot pedal that needs to be pressed, along with the exposure buttons, during the acquisition.

The exposure controls can be set using either of two modes: automatic or manual. The automatic mode uses the Automatic Optimization of Parameters (AOP), which selects the kV, mAs, and target / filter combination. In the manual mode, the operator chooses the parameters.

For thin breasts, the molybdenum (Mo) target is used with a Mo filter. For breasts just smaller than average, the Mo target is used with a rhodium (Rh) filter. The Rh target is used for thicker breasts, in combination with a Rh filter.

The Senographe Essential has a caesium iodide (CsI) detector with a 100-micron resolution. This resolution remains the same throughout the image series, as no pixel binning is performed. A special grid is used for tomosynthesis and remains in position throughout the exposure.

During tomosynthesis, the tube head moves across an arc of 25º and acquires nine projections of the compressed breast at 3.1º intervals. Tube motion stops for each exposure to avoid image blur. Raw data from these images is automatically reconstructed using Adaptive Statistical Iterative Reconstruction (ASiR) to produce a tomosynthesis image of the breast. The nine raw images produced during the acquisition are sent immediately to the acquisition workstation (AWS), so that the operator can confirm adequate positioning. With the SenoClaire, these images are only projections, whereas with other tomosynthesis systems, the reconstructed planes are shown on the AWS. The low doses of these images, which are each one ninth of the total dose, make them appear grainy, as mentioned in the comments in Section 7. The acquisition time is less than 10 seconds for an average breast of 45mm thickness.

1.2.4 Image Reading

The tomosynthesis images are transferred to the dedicated Image Diagnost International (IDI) reporting workstation where reading takes place. The images (referred to as “volume data”) can be viewed in two formats: slabs (10mm thick and spaced 5mm apart, overlapping) or planes (0.5mm or 1mm apart). The average number of planes and slabs are 50-100 and 10, respectively. The raw projection images are transferred directly to the main PACS at both sites. Tomosynthesis images are not stored and could be generated again from these at a later date, if required.

A 2D synthetic image can be produced from the tomosynthesis data at the IDI workstation, by applying a processing algorithm, but this was not evaluated.

1.3 Practical considerations

At the time of the evaluation, tomosynthesis had already been in use in Derby for selected symptomatic cases, following protocols agreed with the local hospital trusts. The radiographers and radiologists already had considerable experience with the equipment. Additional training in image reconstruction from PACS was only given to senior staff, due to clinical pressures on staff in different areas.

1.3.1 Image acquisition

In Derby there were only two mammography systems within the clinical area of the department. The use of stereo biopsy equipment and acquisition of additional spot compression views in the centre were restricted to a single system, since they could not be performed on the other one when it was set up for use in tomosynthesis mode.

In Nottingham, women had to be moved between areas if biopsy or additional views were required.

More details of the practical arrangements at the two sites are given in Sections 4.5 and 4.6.

1.3.2 Staffing of assessment clinics

About 20 women usually attended the assessment clinics. Between six and eight of these were normally selected for tomosynthesis.

The assessment clinics were held on one day a week: Tuesday in Derby and Wednesday in Nottingham. In Derby, the clinics were managed with two radiologists and two advanced practitioners and one radiographer. In Nottingham, the assessment

clinics were run with two radiologists and two or three radiographers. At both sites, there were supporting staff and a research radiographer to consent the women.

1.4 Objectives of the evaluation

The primary objective of the evaluation was to establish the performance and serviceability of the GE SenoClaire digital breast tomosynthesis system for women who have been recalled for further examination following mammographic screening:

- to evaluate the function and reliability of the equipment when used for tomosynthesis
- to assess the practical aspects of the equipment in an assessment clinic setting
- to report the experiences and comments of radiographers and radiologists on the use and value of the system during assessment, including image quality and practical aspects of image review
- to report the radiation dose to the breast for the women imaged during the evaluation

2. Acceptance testing, commissioning and performance testing

2.1 Acceptance testing and commissioning

The GE Essential systems at Nottingham and Derby were commissioned at different times. The systems were upgraded and configured for both digital breast tomosynthesis and 2D digital mammography.

Acceptance testing and commissioning for both sites was carried out by the Northampton medical physics service following the NHSBSP protocol[6] for tomosynthesis testing which was still in draft at the time. The tests included measurement of dose and image quality, in both conventional and tomosynthesis modes. The results of the commissioning tests are presented at Appendix 1.

Tests were also performed to assess the functionality of the MTD in 2D mode following protocols for FFDM systems.[7, 8] The results indicated that its performance is broadly similar to that of the standard 2D Bucky. The MTD was not used in 2D mode during the trial at either site, but a short evaluation of its use for symptomatic women is presented in Section 4.9.

The IDI workstations each have two 5MP Barco Coronis MDMG-5121 displays. They were tested following the NHSBSP equipment guidance[6] and were found to be satisfactory.

2.1.1 Derby

In Derby, the GE Essential was originally installed in 2007. The system was upgraded in July 2013, with a new detector installed, prior to being used for tomosynthesis. The SenoClaire digital breast tomosynthesis system was installed in January 2014. The system was already integrated with the local PACS at the time of the evaluation.

2.1.2 Nottingham

In Nottingham, the GE Essential was installed in May 2013. The system was upgraded with the SenoClaire digital breast tomosynthesis system in October 2013. The installation included integration with the local PACS.

This system was the one used for the technical evaluation of the GE Healthcare SenoClaire digital breast tomosynthesis system[5].

2.2 Six-monthly performance testing

The tomosynthesis tests were repeated at six-monthly intervals during the trial period. The 2D performance was tested at the same intervals, in both conventional mode and with the MTD.

Results of the first six-monthly tests are presented in Appendix 1. These tests were carried out in March 2014 for Nottingham and July 2014 for Derby.

3. Routine quality control

The routine quality control (QC) during the evaluation was mainly carried out using the GE in-built Quality Assurance Procedures (QAP) tests for both 2D exposures and tomosynthesis.[9,10] These correspond to the majority of the physics and radiographer tests in the NHSBSP guidelines for 2D and tomosynthesis exposures.[6-8, 11, 12] However, the NHSBSP protocol for the routine testing of tomosynthesis systems[11] had not been published at the time of the evaluation. The daily tests described in it were not carried out at the evaluation sites until 2015, after the completion of the evaluation.

Daily, weekly and monthly QC tests are described in Sections 3.2 to 3.4. In a few cases, only results from Nottingham are presented because not all the tests were carried out at Derby during the evaluation period. GE tests which do not correspond to any of those in the NHSBSP guidelines are presented in Appendix 3.

3.1 GE QAP tests

The GE Breast Tomosynthesis QC manual is an addendum to the Senographe Essential QC manual. All tests are performed with the MTD installed, operating in either 2D or tomosynthesis mode. The 2D tests are a subset of the GE QAP tests for 2D imaging, with the addition of the grid texture test.

The GE QAP tests and their minimum frequency are shown in Table 1.

Table 1. GE QAP tests

Frequency	Weekly	Monthly
2D tests with MTD	Contrast-to-noise ratio (CNR)	Signal-to-noise ratio (SNR)
	Modulation transfer function (MTF)	Grid texture
	Phantom image quality (IQ)	Automatic optimisation of parameters (AOP)
Tomosynthesis tests	Phantom IQ	AOP
	Flat field test	

For all QAP tests, except Phantom IQ, the operator selects the test from the QAP menu in the browser screen and then follows the on-screen instructions. On completion of the test, the results are displayed on-screen with the relevant limits and Pass/Fail status. If the results are out of limits, the test is repeated, as recommended in the GE manual,

after first checking the test conditions and allowing the detector to warm up for at least ten minutes.

Results were recorded electronically during the evaluation and sent to the local Medical Physics service.

3.2 Daily QC tests

3.2.1 Daily test – 2D exposure and artefacts

A 2D exposure of a 45mm thick block of Perspex is made under automatic exposure control, with the paddle in place. The exposure factors are recorded. The mean pixel value and SNR are determined in a central region of the image. The images are examined for artefacts and a log is kept.

The test results are shown in Figures 5 to 10. All the values remained within the NHSBSP remedial limits (±10% of baseline). No artefacts were seen.

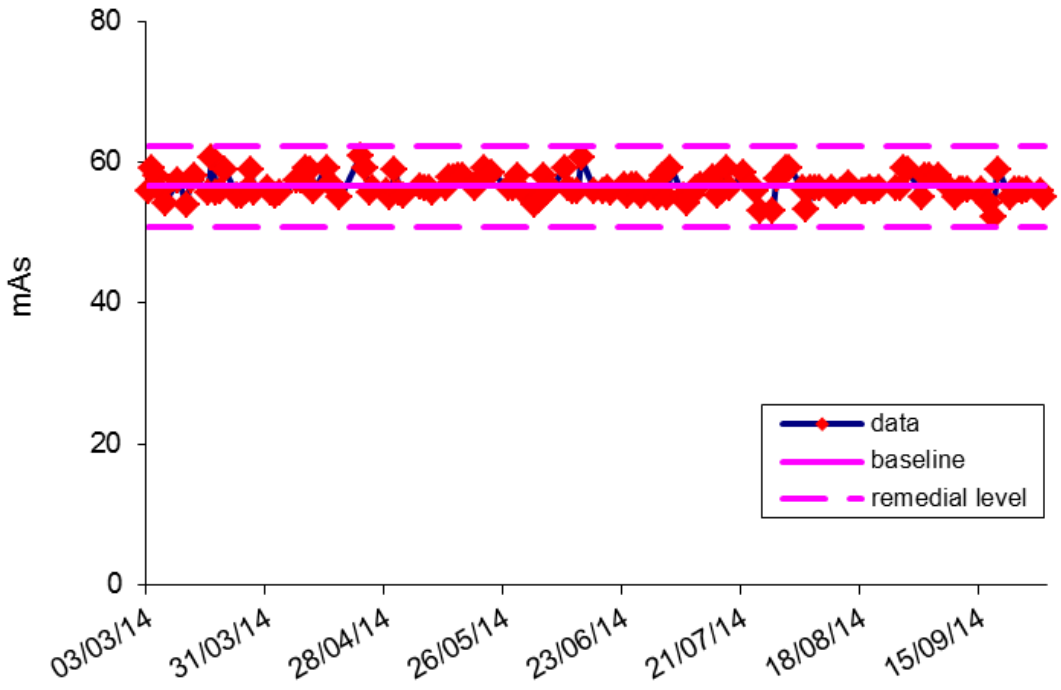

Figure 5. mAs recorded daily at Derby for 45mm of Perspex (2D)

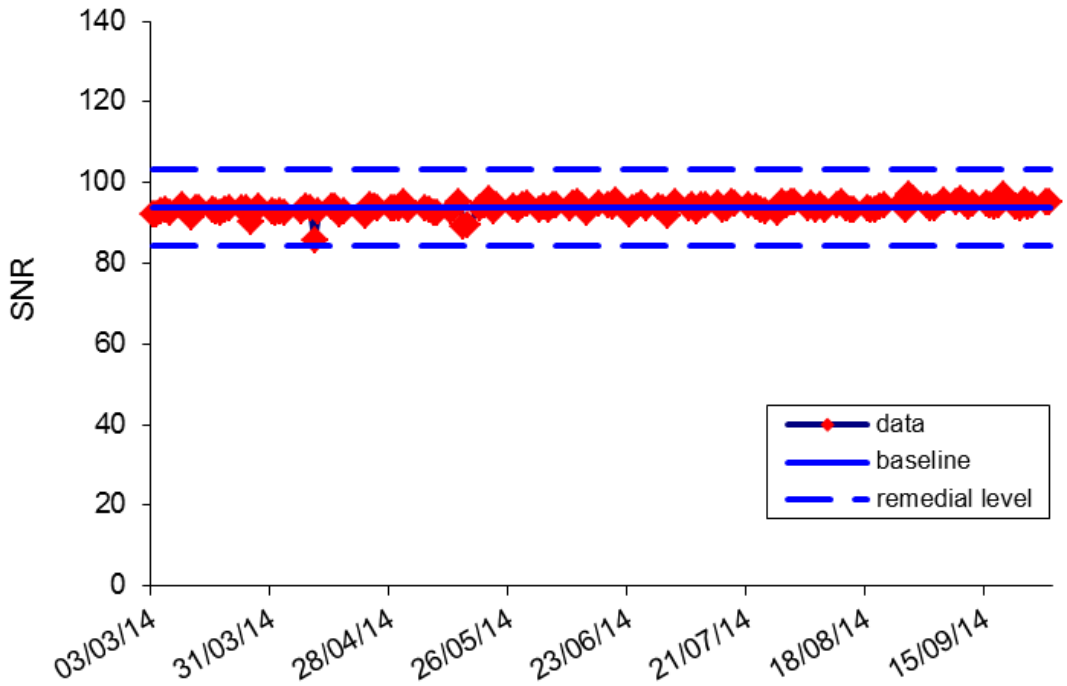

Figure 6. SNR recorded daily at Derby for 45mm of Perspex (2D)

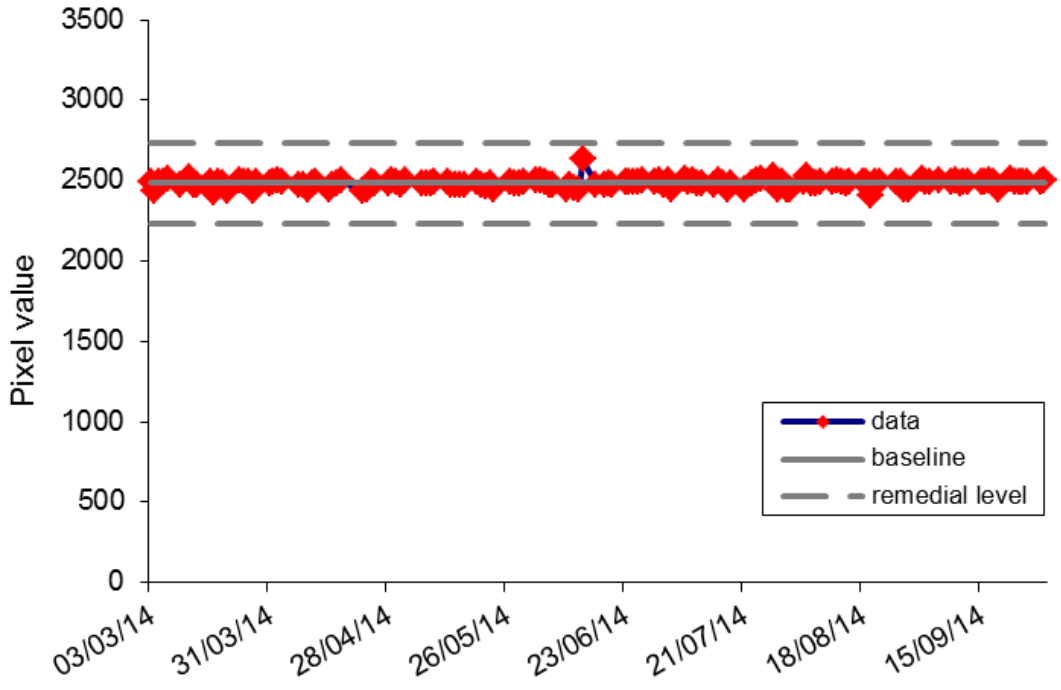

Figure 7. Pixel value recorded daily at Derby for 45mm of Perspex (2D)

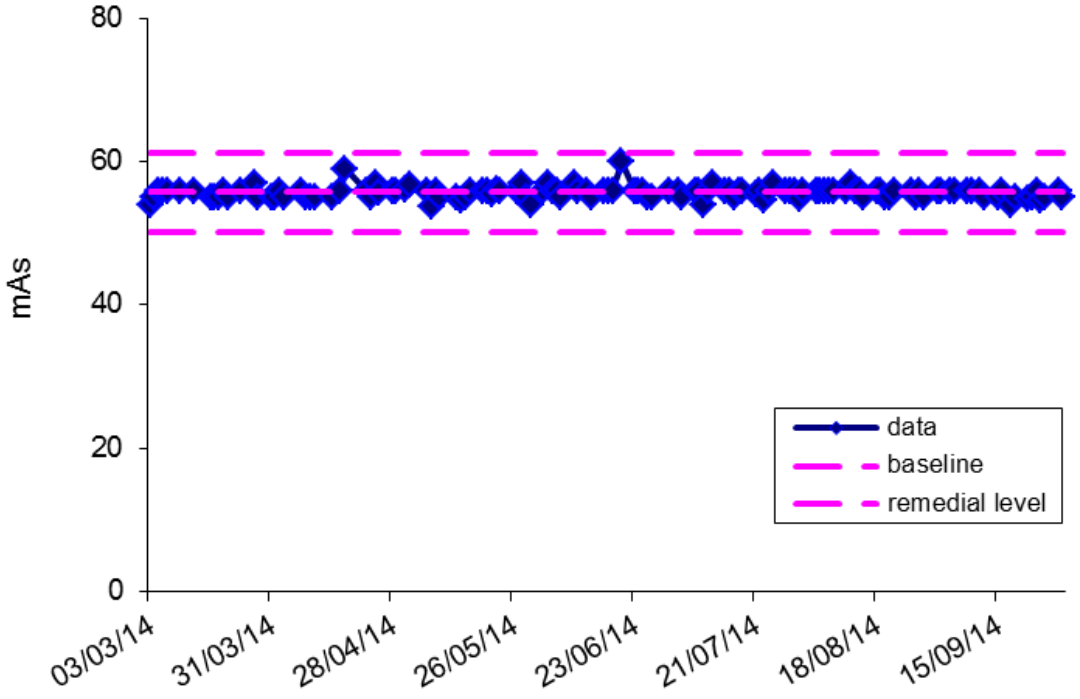

Figure 8. mAs recorded daily at Nottingham for 45mm of Perspex (2D)

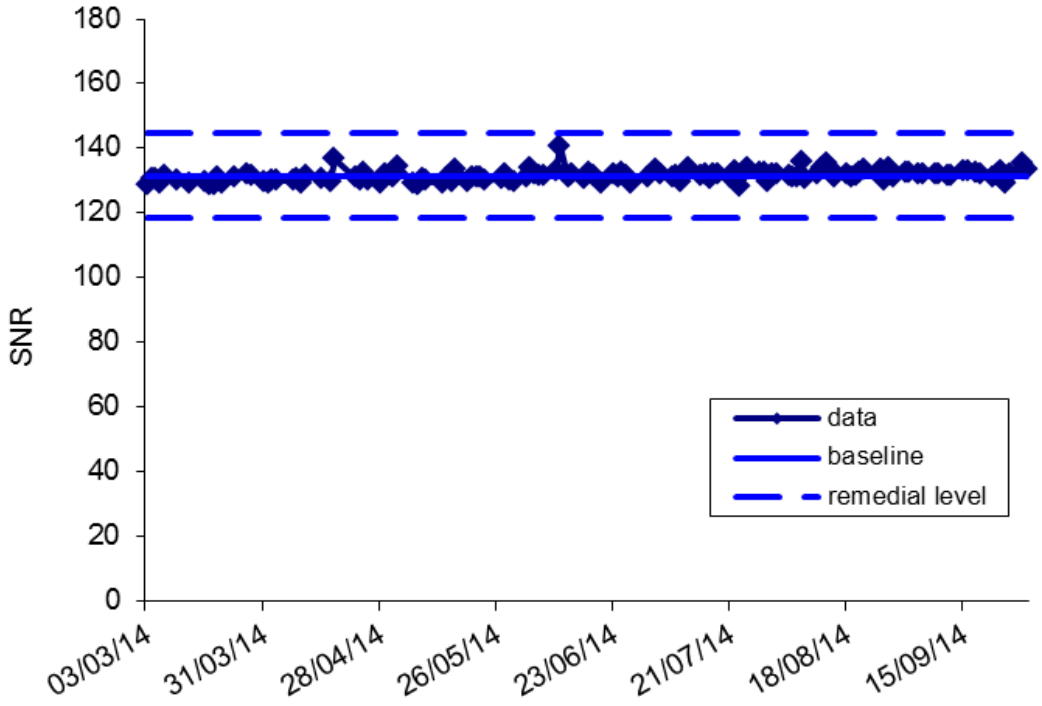

Figure 9. SNR recorded daily at Nottingham for 45mm of Perspex (2D)

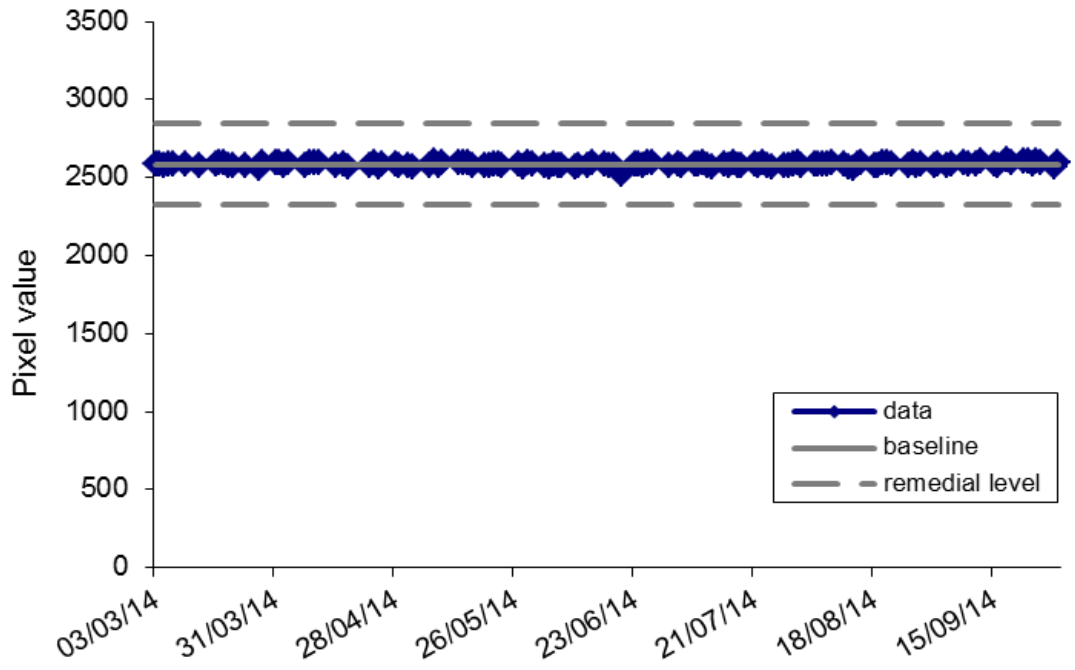

Figure 10. Pixel value recorded daily at Nottingham for 45mm of Perspex (2D)

3.2.2 Daily test – tomosynthesis exposure and artefacts

The test procedure is the same as in Section 3.2.1, but with a tomosynthesis exposure. The mean pixel value and SNR are determined in a reconstructed plane at a fixed height.

Although the results in this section are not for the period of the evaluation, they show that the SenoClaire tomosynthesis system is capable of performing reproducibly from day to day.

Reviewing the tomosynthesis images proved challenging in practice as reconstructed images could not be viewed on the acquisition workstation. They could only be reviewed on the IDI workstation, and access to the workstation was difficult in a busy clinical environment. It also took some time for the reconstruction to be completed before the mean pixel value and SNR could be determined.

The reconstructed planes and slabs were inspected for artefacts, with no clinically significant artefacts reported.

The daily test results are shown in Figures 11 to 16. The step change in pixel value and SNR at Nottingham was caused by a software upgrade, when the baseline was reset.

All the values remained within the NHSBSP remedial limits (±10% of baseline for mAs and pixel value and ±20% of baseline for SNR).

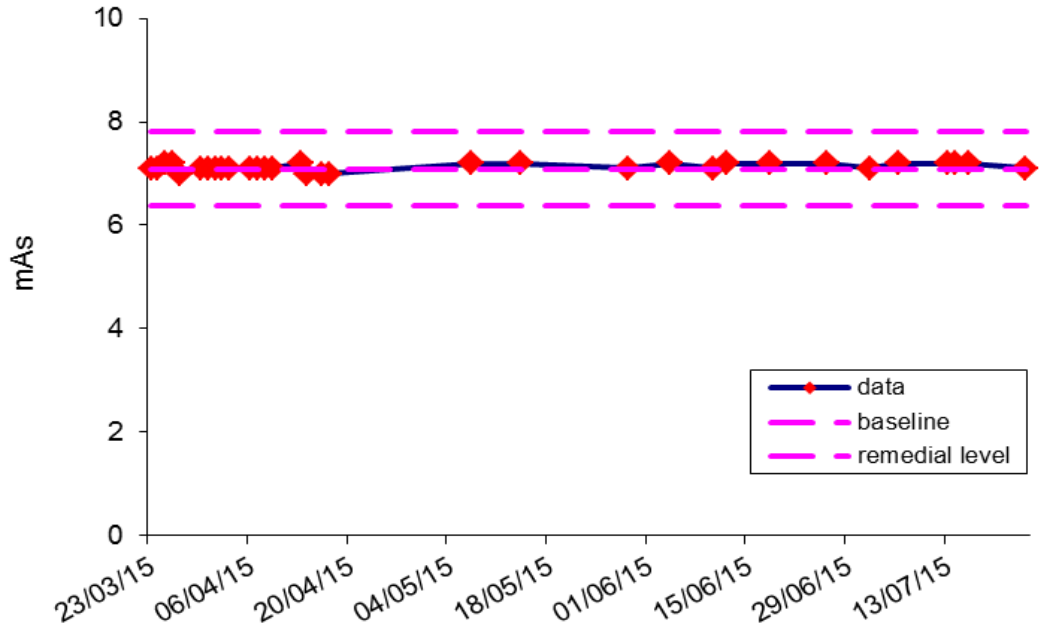

Figure 11. mAs recorded daily at Derby for 45mm of Perspex (tomosynthesis)

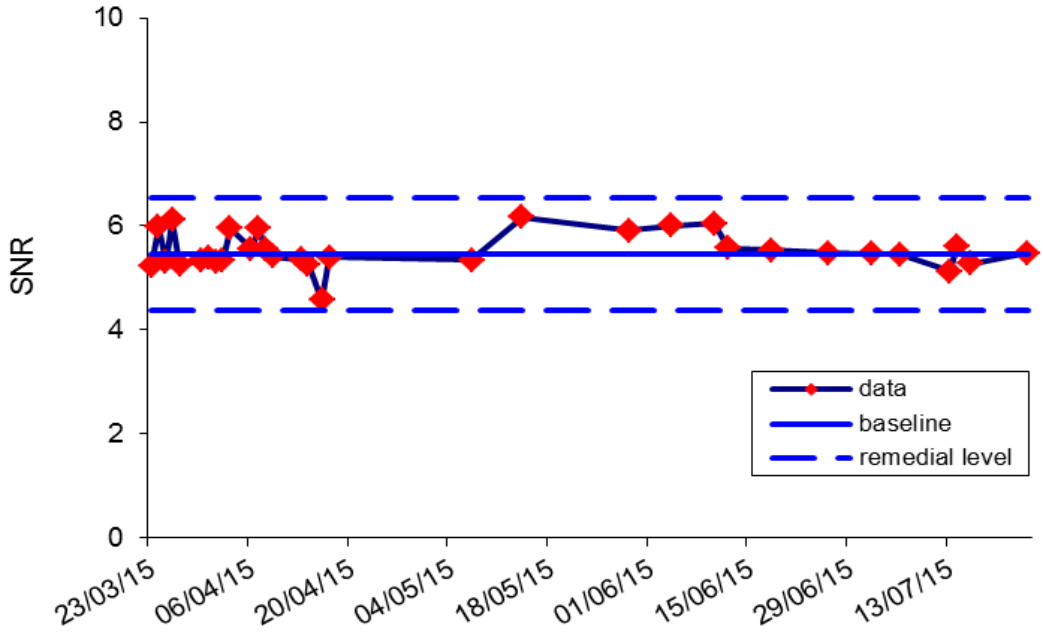

Figure 12. SNR recorded daily at Derby for 45mm of Perspex (tomosynthesis)

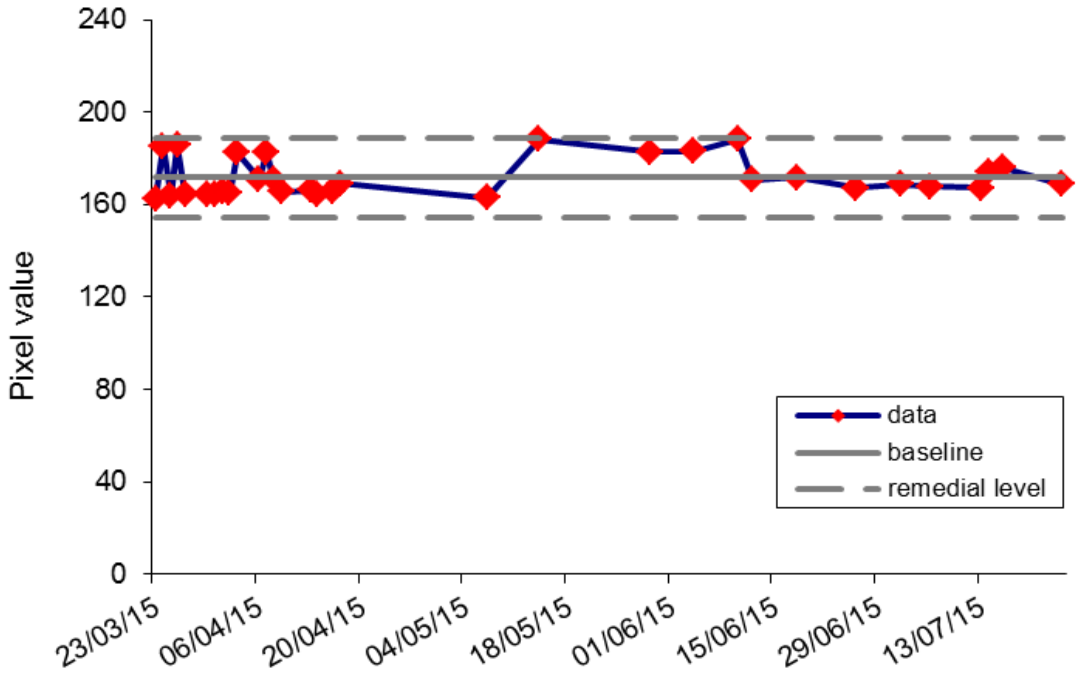

Figure 13. Pixel value recorded daily at Derby for 45mm of Perspex (tomosynthesis)

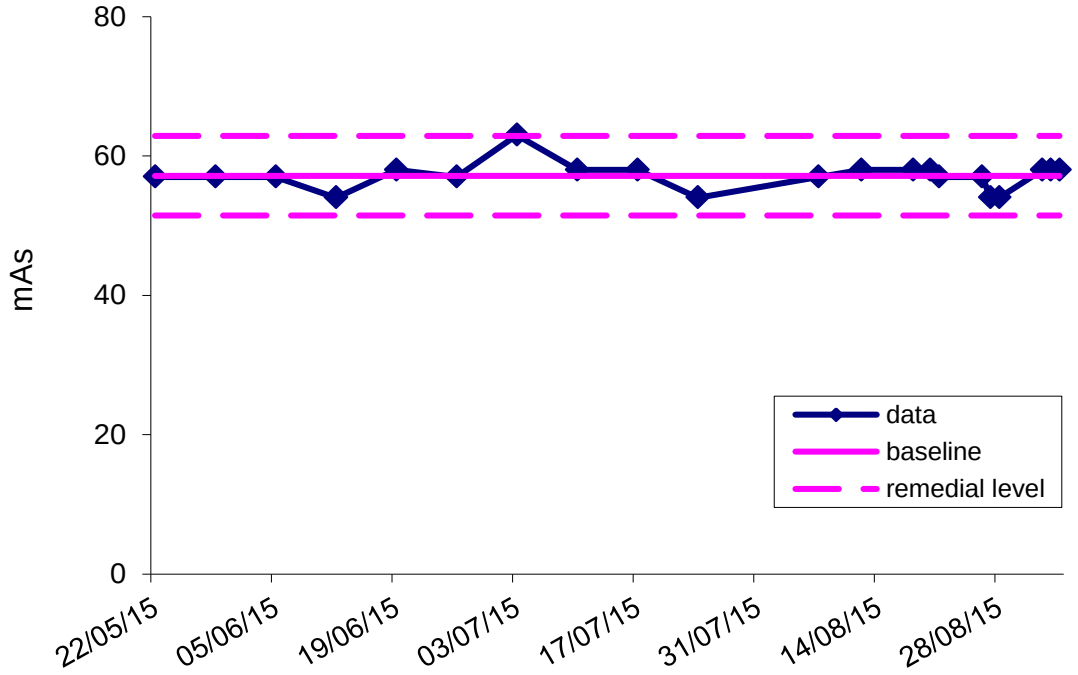

Figure 14. mAs recorded daily at Nottingham for 45mm of Perspex (tomosynthesis)

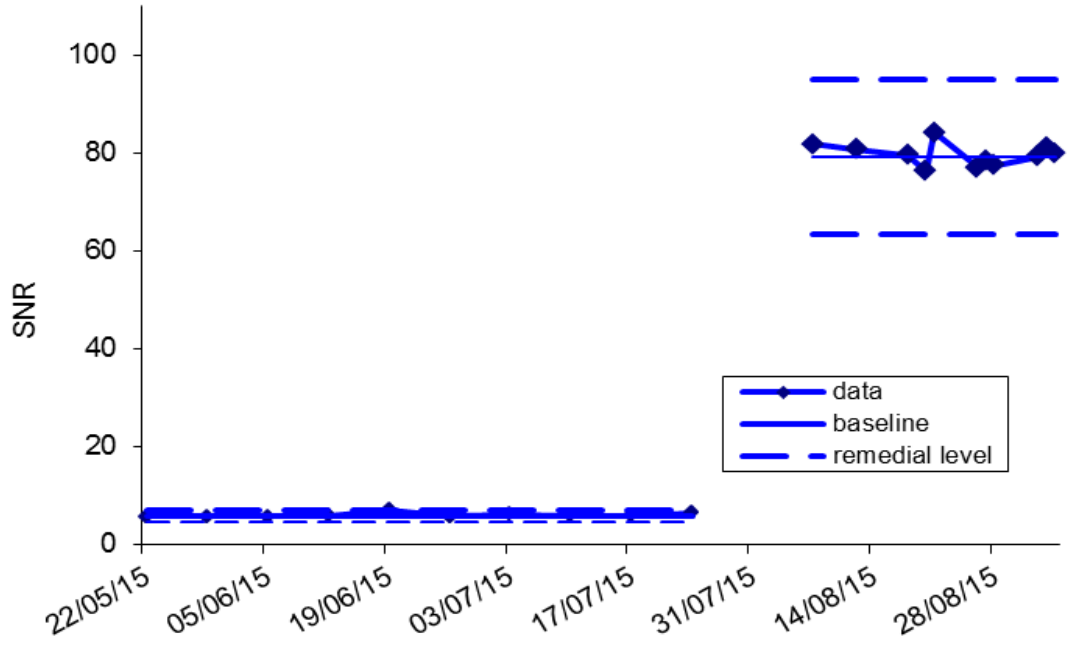

Figure 15. SNR recorded daily at Nottingham for 45mm of Perspex (tomosynthesis)

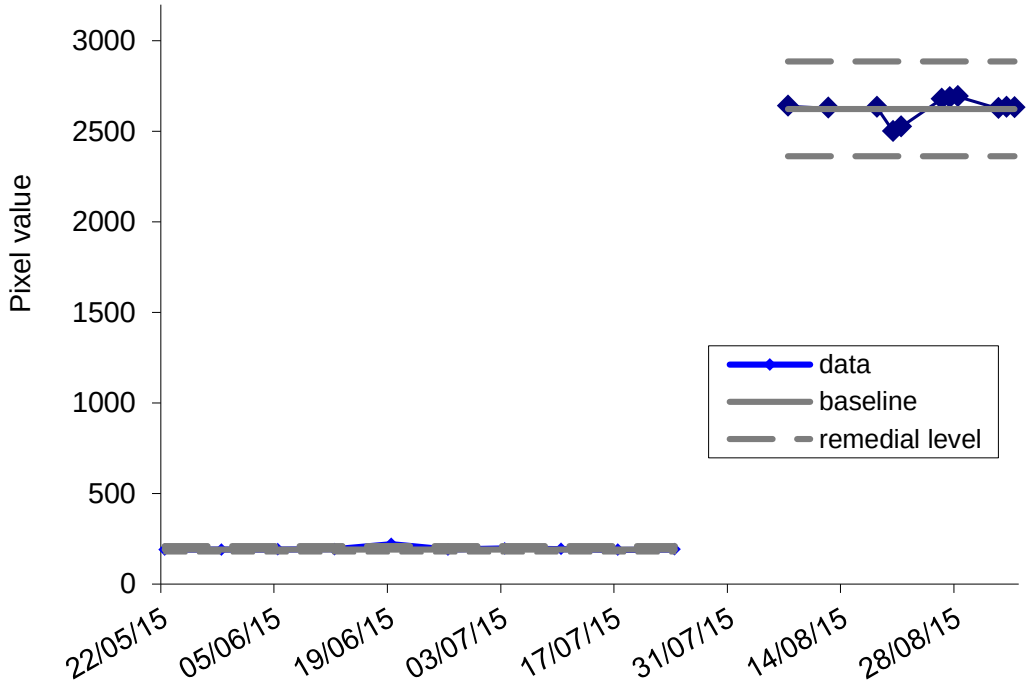

Figure 16. Pixel value recorded daily at Nottingham for 45mm of Perspex (tomosynthesis)

3.3 Weekly QC tests

3.3.1 GE tests – 2D

3.3.1.1 CNR

The phantom is an IQST device, supplied by GE. This is placed on the MTD and “CNR and MTF Tests” is selected from the QAP menu. The system selects the exposure factors automatically, and an exposure is made.

The CNR results are shown in Figures 17 and 18. CNR values at both sites were consistent and within the NHSBSP remedial limits (±10% of baseline) throughout the evaluation period. The MTF results, produced in the same test, are at Appendix 3.

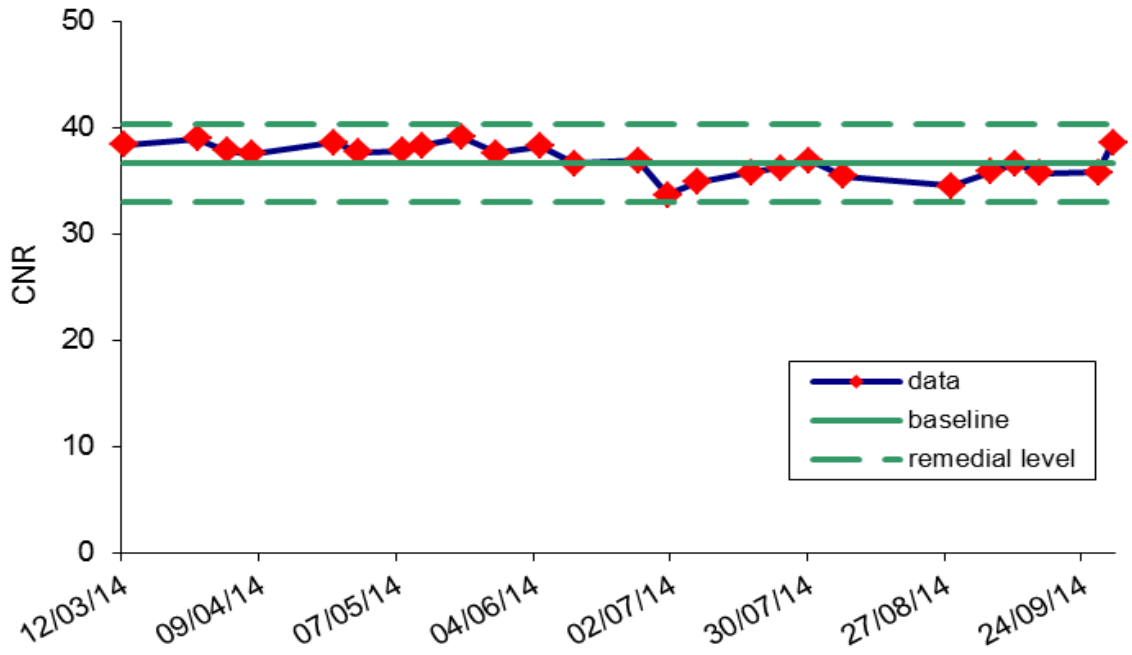

Figure 17. GE QAP weekly CNR measurements at Derby (2D)

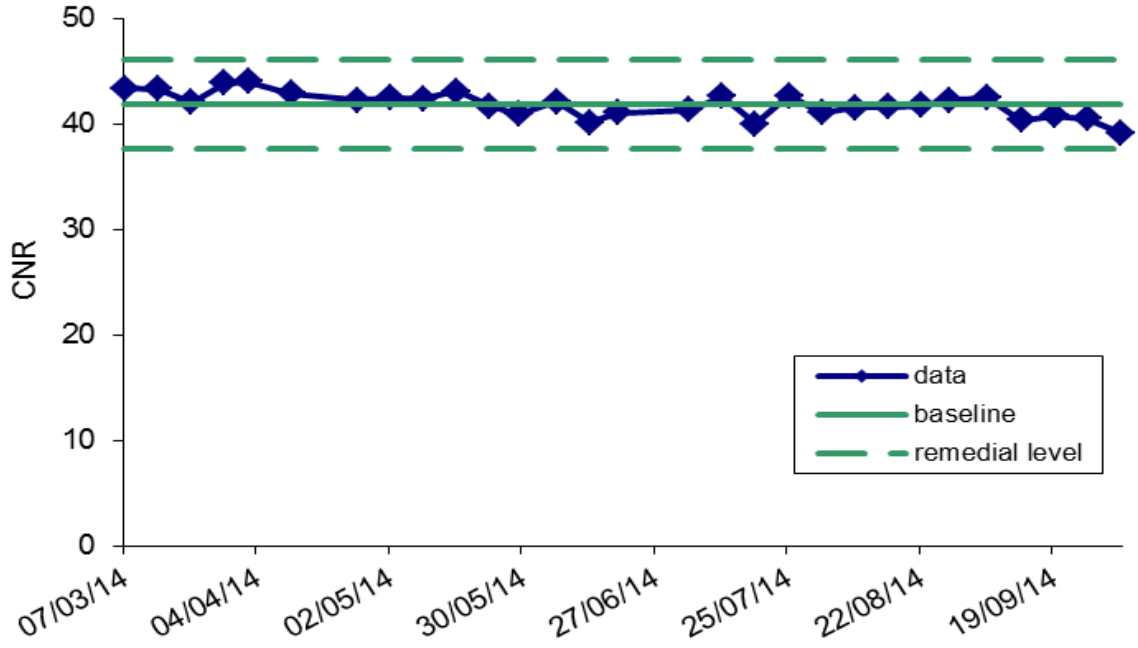

Figure 18. GE QAP weekly CNR measurements at Nottingham (2D)

3.3.1.2 Image quality

GE supplies an ACR phantom for this test. It contains fibres, masses and calcifications, and its use is therefore similar to that of the TORMAM in the NHSBSP protocol. An exposure is made and the image is scored on the monitor of the AWS.

Results from Nottingham, Figure 19, show that the scores for image quality (fibres, calcifications and masses) remained the same throughout the evaluation period. The dotted line is the minimum limit of 10 for the total score, which is achieved in all cases. The individual minimum values (not shown) are 4 for fibres, 3 for calcifications and 3 for masses.

There are no results for Derby as this test was not carried out there. However, both centres later started weekly image quality testing with the TORMAM. Results are not presented here.

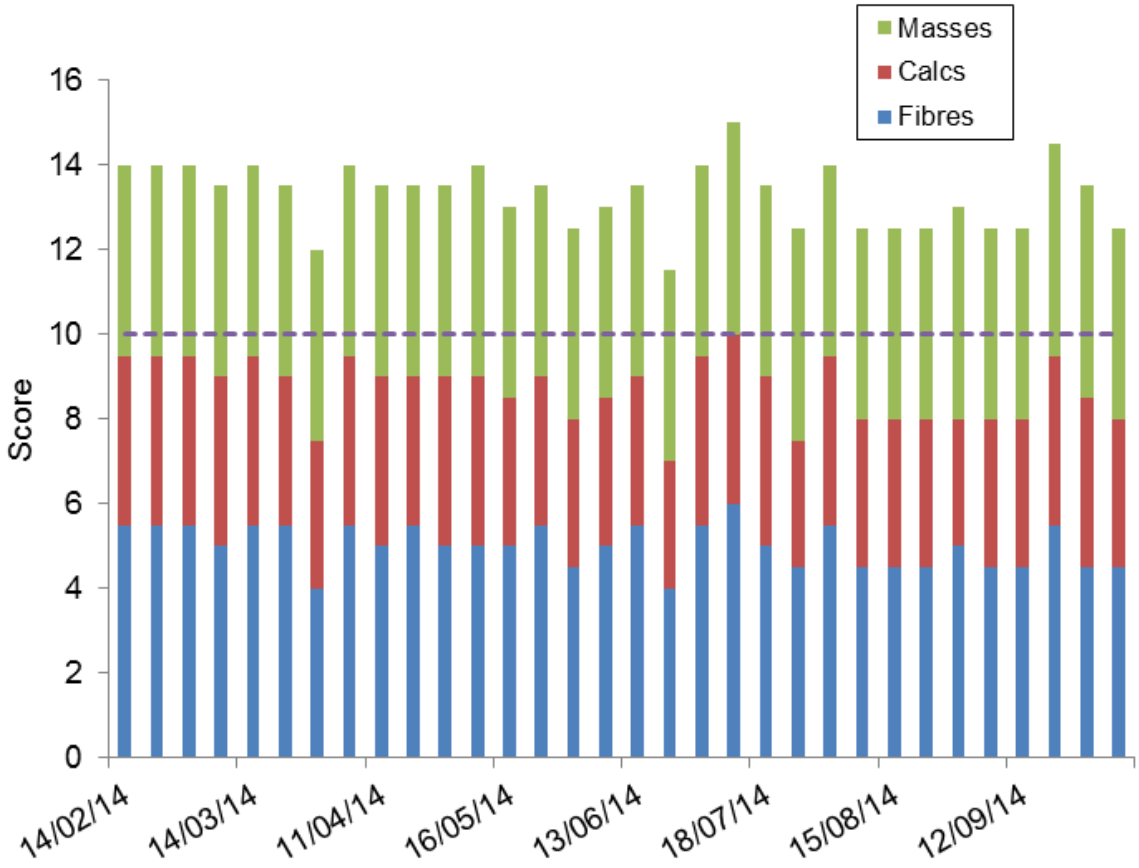

Figure 19. GE QAP weekly ACR phantom IQ test at Nottingham (2D)

3.3.1.3 Uniformity check

The NHSBSP test for uniformity of the 2D image was not performed, as the tests in Appendix 3 provide information on the uniformity of the image (Sections A3.1 to A3.4).

3.3.2 GE test – image quality in tomosynthesis mode

The test is carried out as in Section 3.3.1.2, except that a tomosynthesis exposure is made and the reconstructed volume is reviewed at the IDI reporting workstation. The image is scored in the plane of best focus.

The results from Nottingham in Figure 20 show that the image quality remained almost the same throughout the evaluation period, and above the minimum total score of 10.

There are no results for Derby as the test was not carried out there. After the evaluation period, Derby introduced image quality checks using the TORMAM.

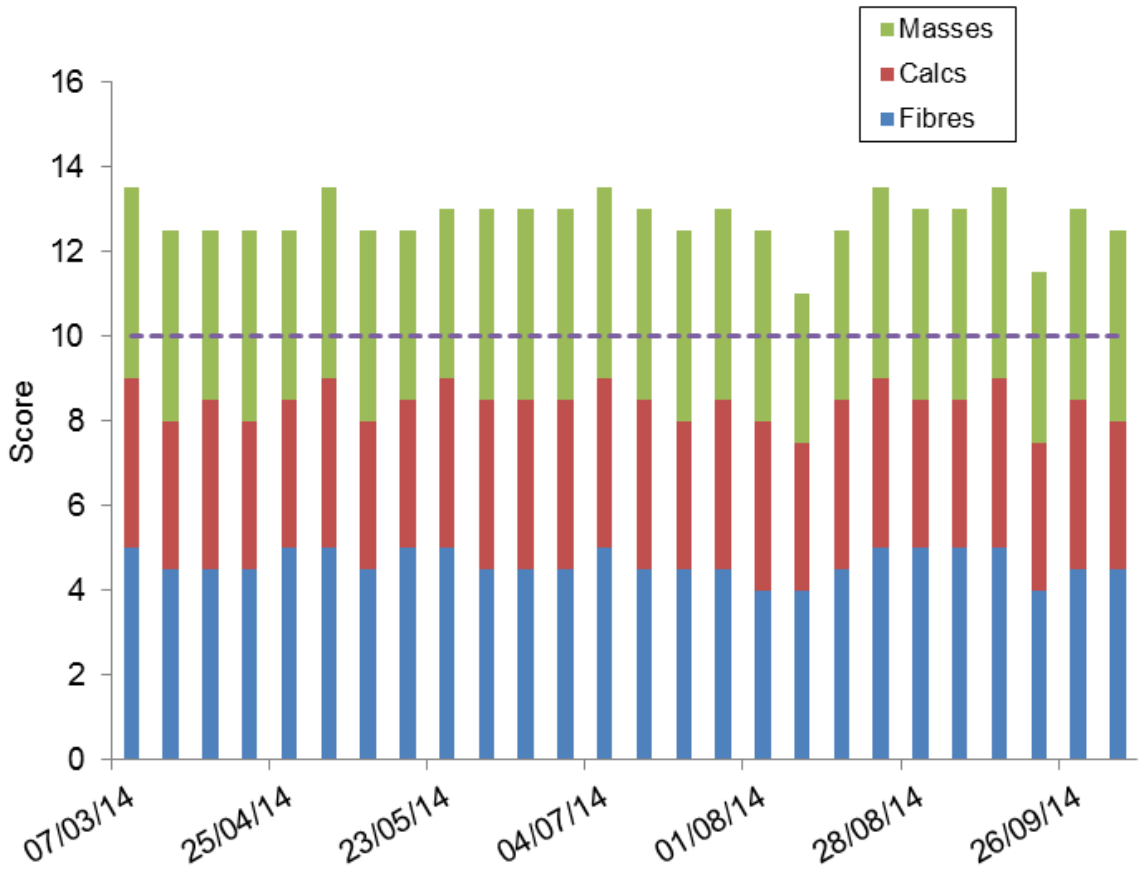

Figure 20. GE QAP weekly ACR phantom IQ test at Nottingham (tomosynthesis)

3.4 Monthly QC tests

3.4.1 GE tests – AOP in 2D

Perspex blocks of thickness 25, 50 and 60mm are supplied by GE for the monthly tests. The test is designed to check the choice of exposure parameters and the SNR. The blocks are exposed in AOP mode, and the exposure parameters are recorded.

Table 2. Exposure parameters recorded and GE action limits for 2D exposure (MTD)

Perspex thickness (mm)	Exposure parameters		GE action limits		
	Derby	Nottingham	kV	Target / filter	mAs
25	26kV Mo / Mo	26kV Mo / Mo	26	Mo / Mo	20-60
50	29kV Rh / Rh	29kV Rh / Rh	29	Rh / Rh	40-90
60	30kV Rh / Rh	31kV Rh / Rh	30 or 31	Rh / Rh	60-120

The mAs values are shown in Figures 21 to 26; they are within the GE limits, and also within the NHSBSP remedial limits of ±10%.

Table 2 shows the recorded exposure parameters for 2D using the MTD. The target, filter and kV always agreed with the GE action limits.

The SNR is calculated automatically, and the results are shown in Figures 27 to 32; these are also within the NHSBSP remedial limits of ±10%, and are above the GE (lower) limit.

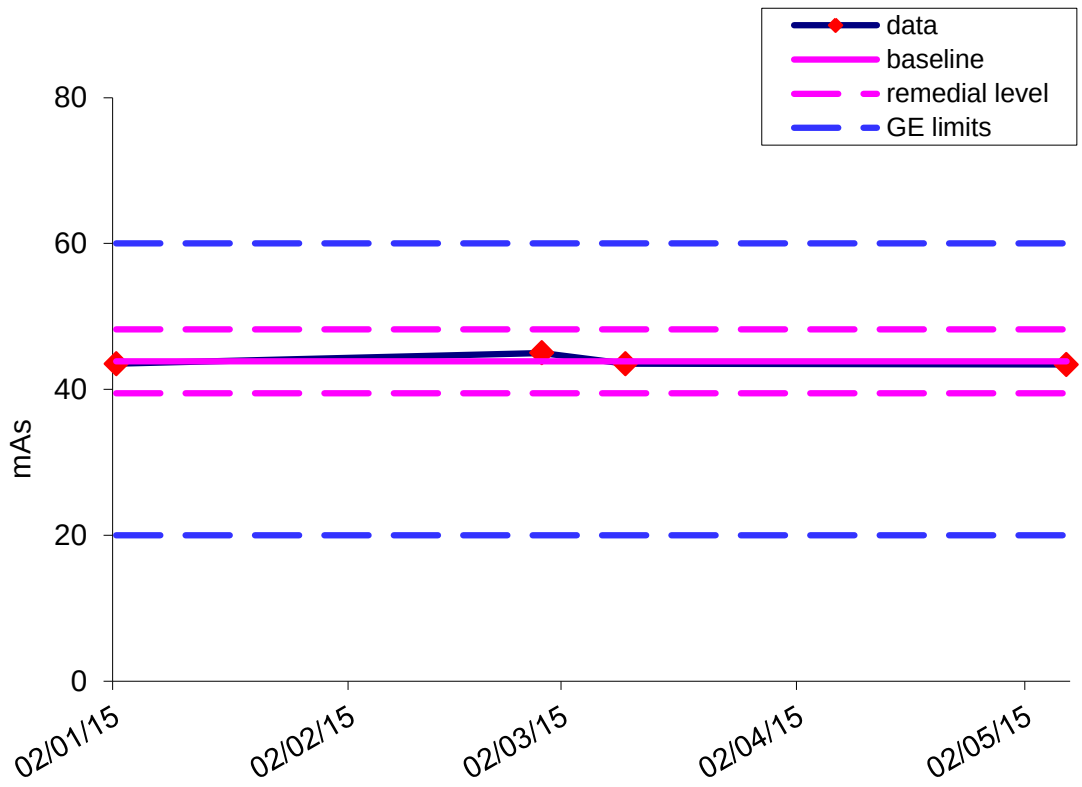

Figure 21. Monthly mAs for 25mm based on GE AOP results at Derby (2D)

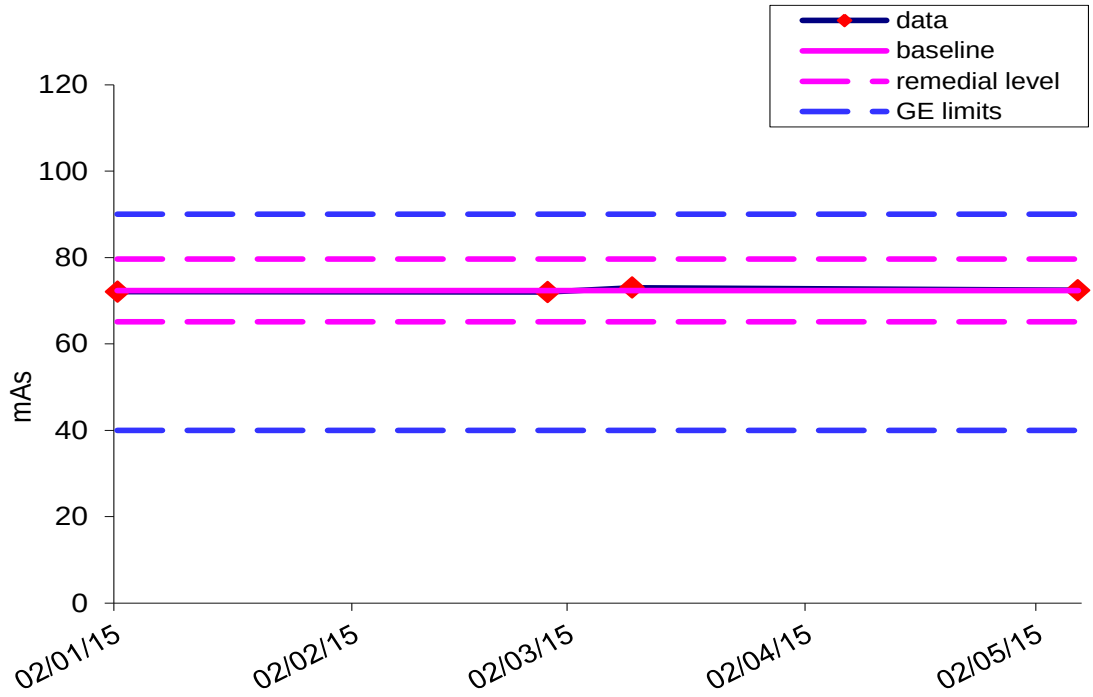

Figure 22. Monthly mAs for 50mm based on GE AOP results at Derby (2D)

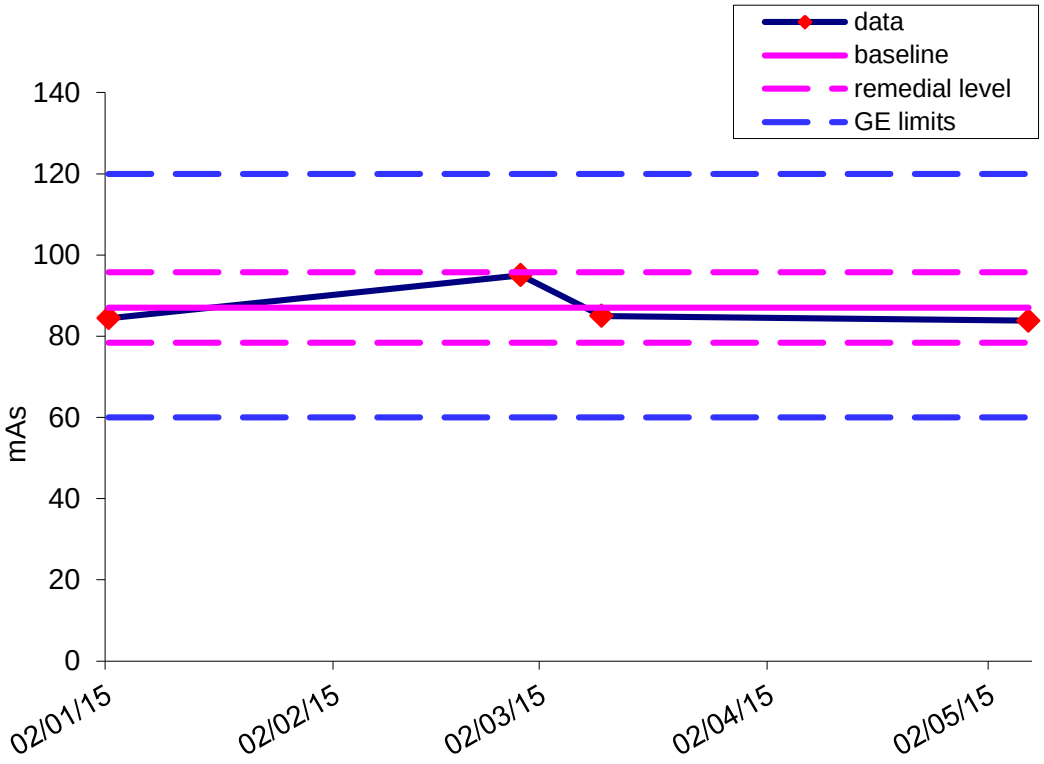

Figure 23. Monthly mAs for 60mm based on GE AOP results at Derby (2D)

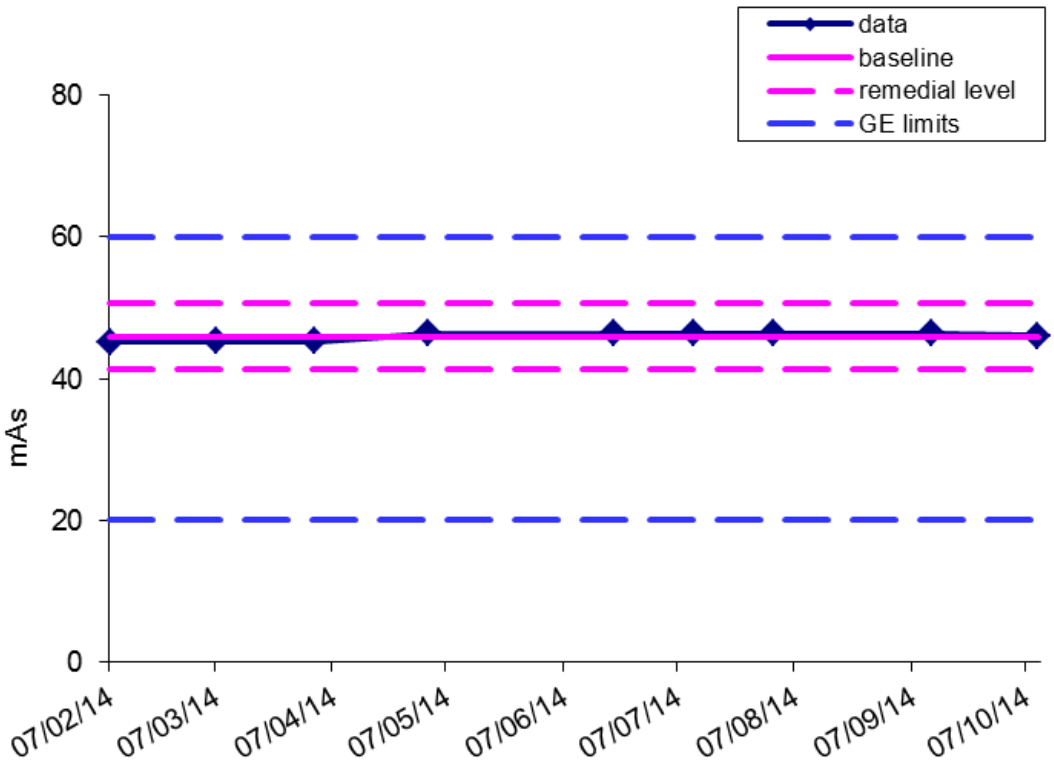

Figure 24. Monthly mAs for 25mm based on GE AOP results at Nottingham (2D)

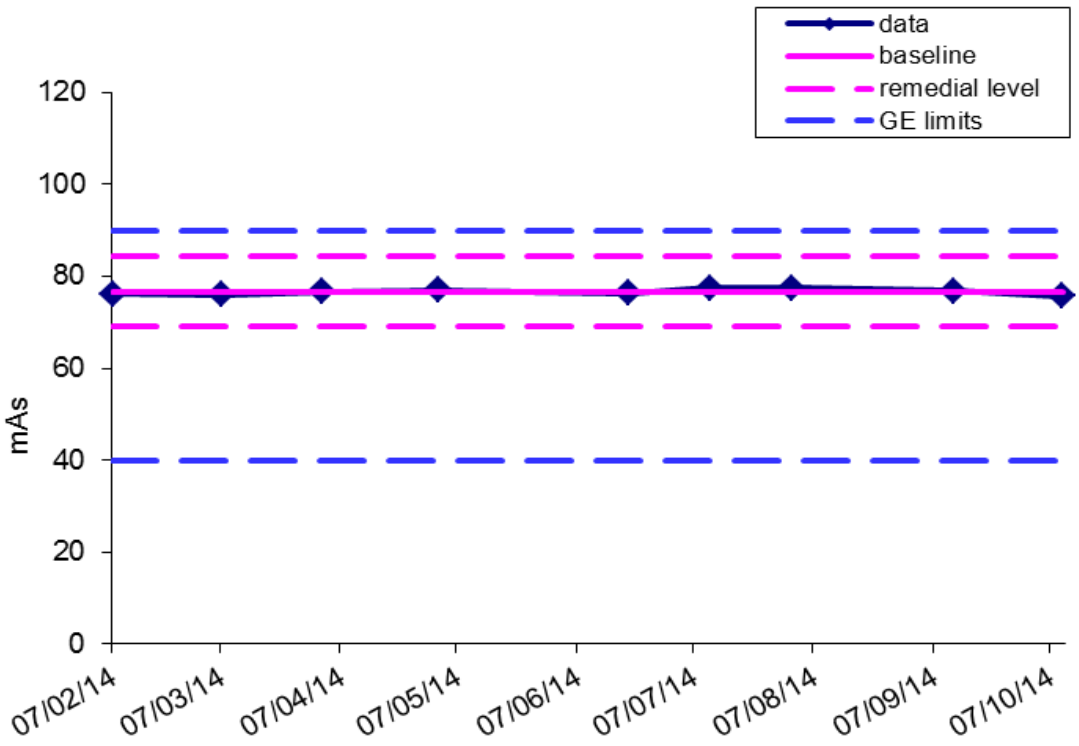

Figure 25. Monthly mAs for 50mm based on GE AOP results at Nottingham (2D)

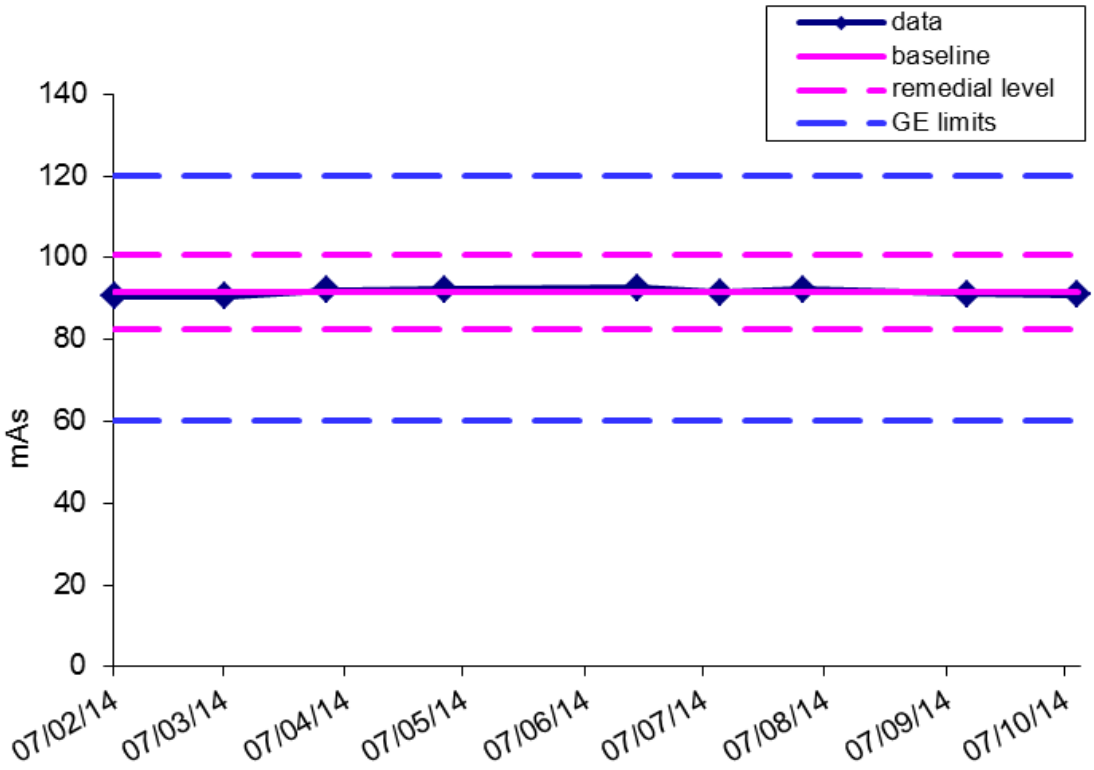

Figure 26. Monthly mAs for 60mm based on GE AOP results at Nottingham (2D)

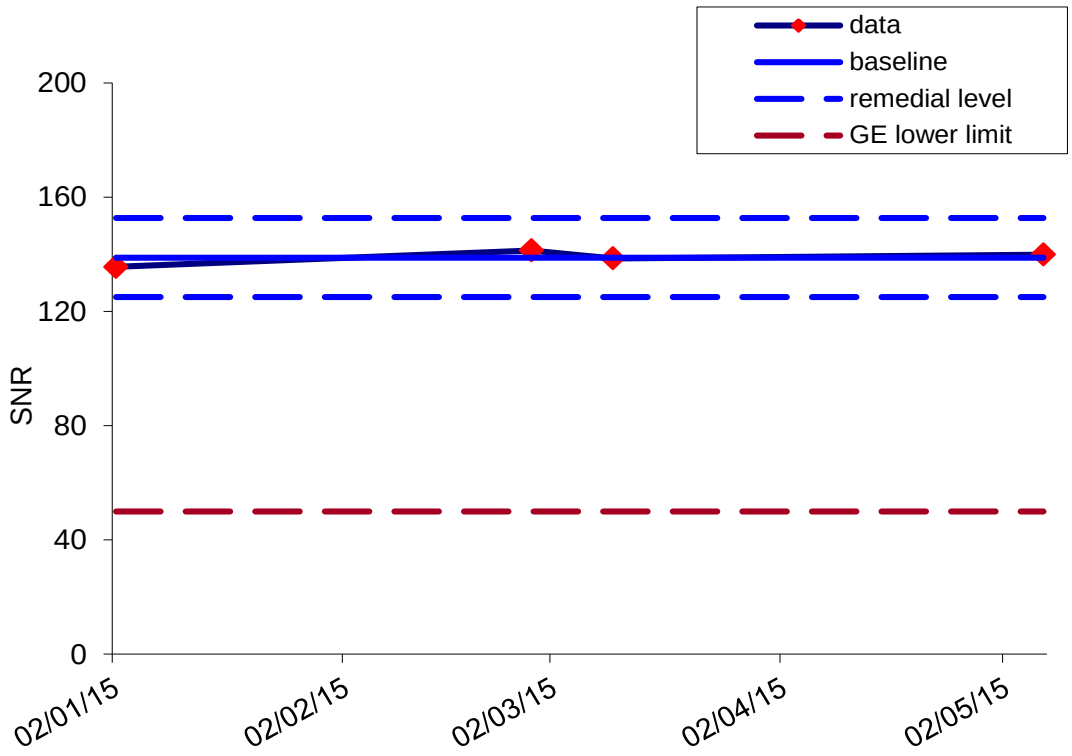

Figure 27. Monthly SNR for 25mm based on GE AOP results at Derby (2D)

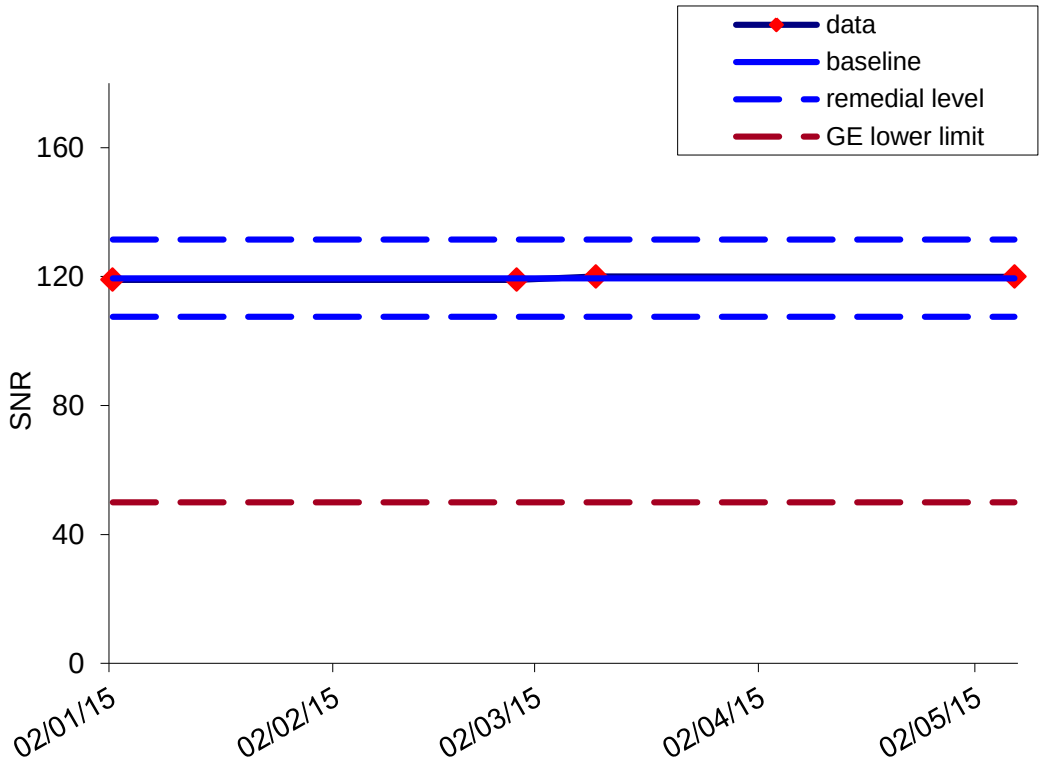

Figure 28. Monthly SNR for 50mm based on GE AOP results at Derby (2D)

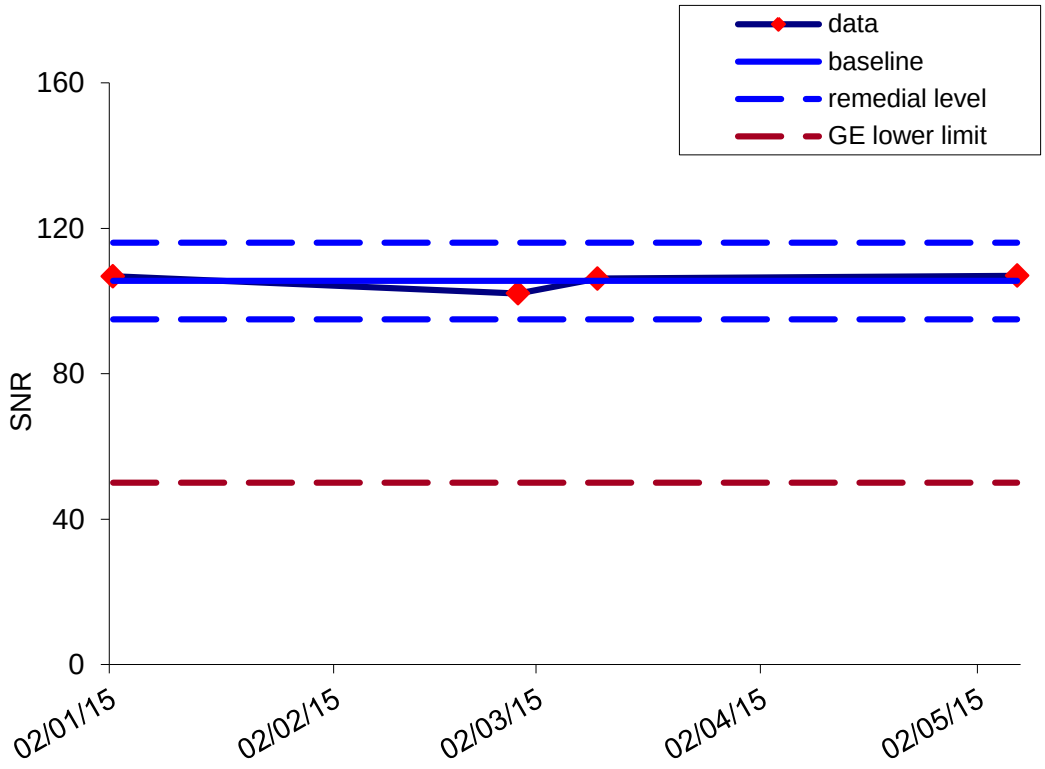

Figure 29. Monthly SNR for 60mm based on GE AOP results at Derby (2D)

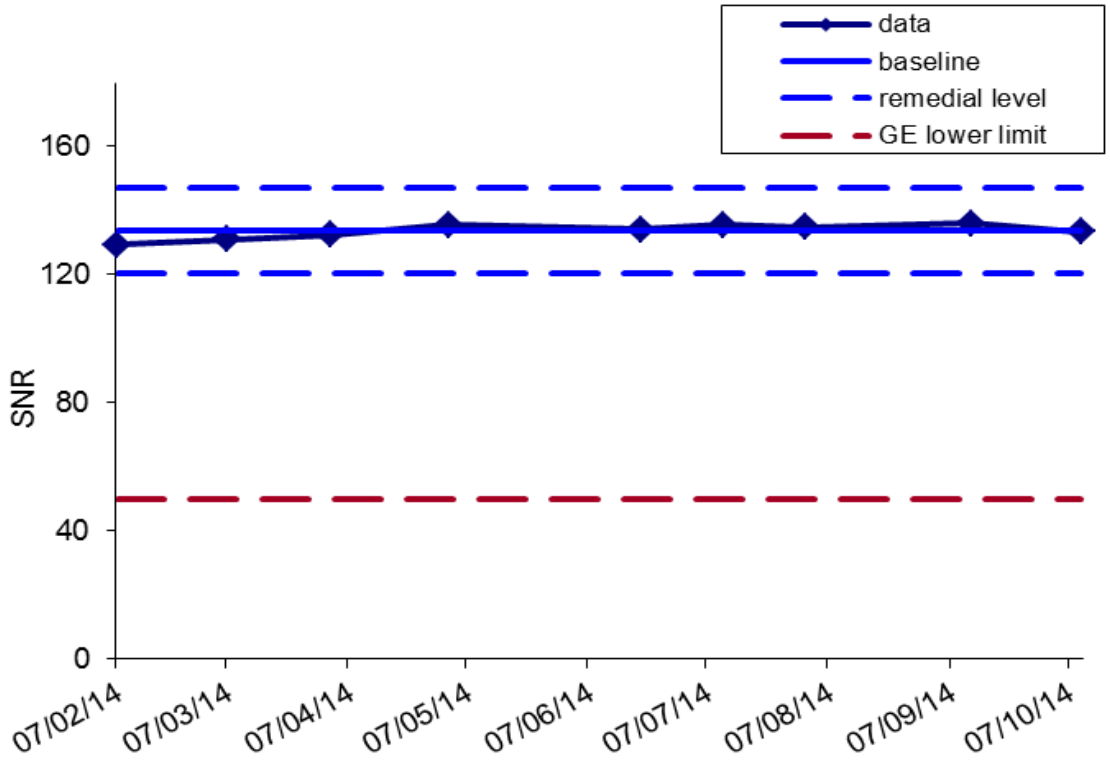

Figure 30. Monthly SNR for 25mm based on GE AOP results at Nottingham (2D)

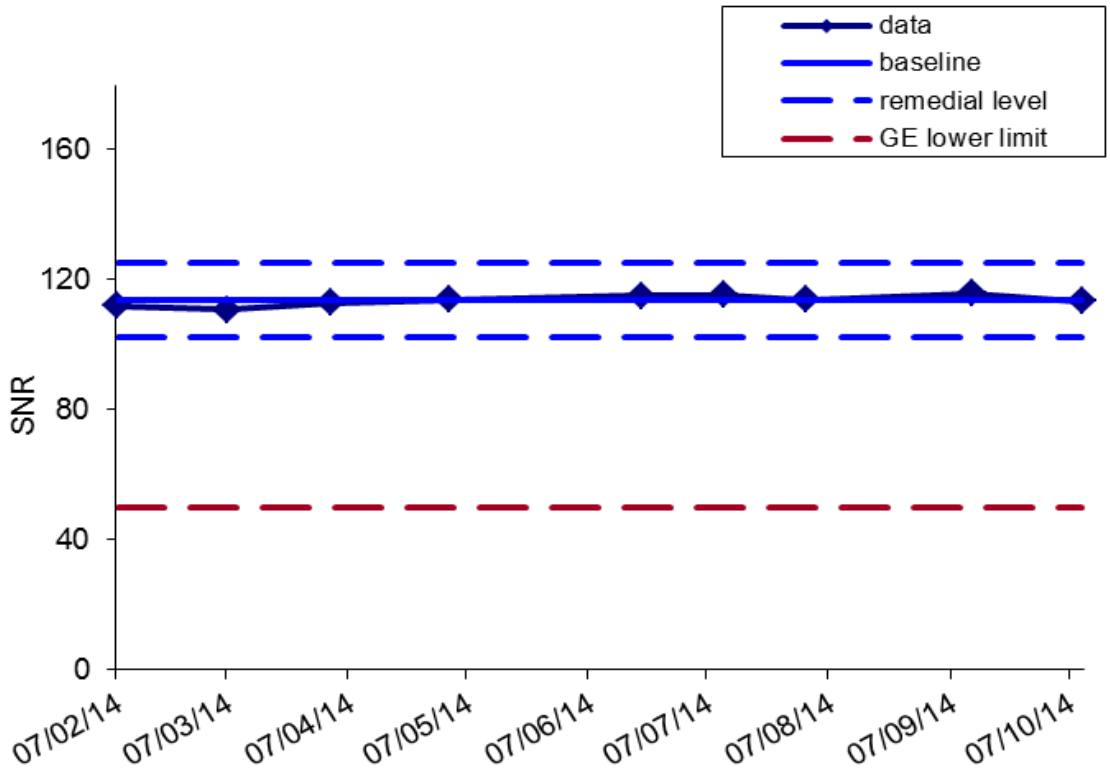

Figure 31. Monthly SNR for 50mm based on GE AOP results at Nottingham (2D)

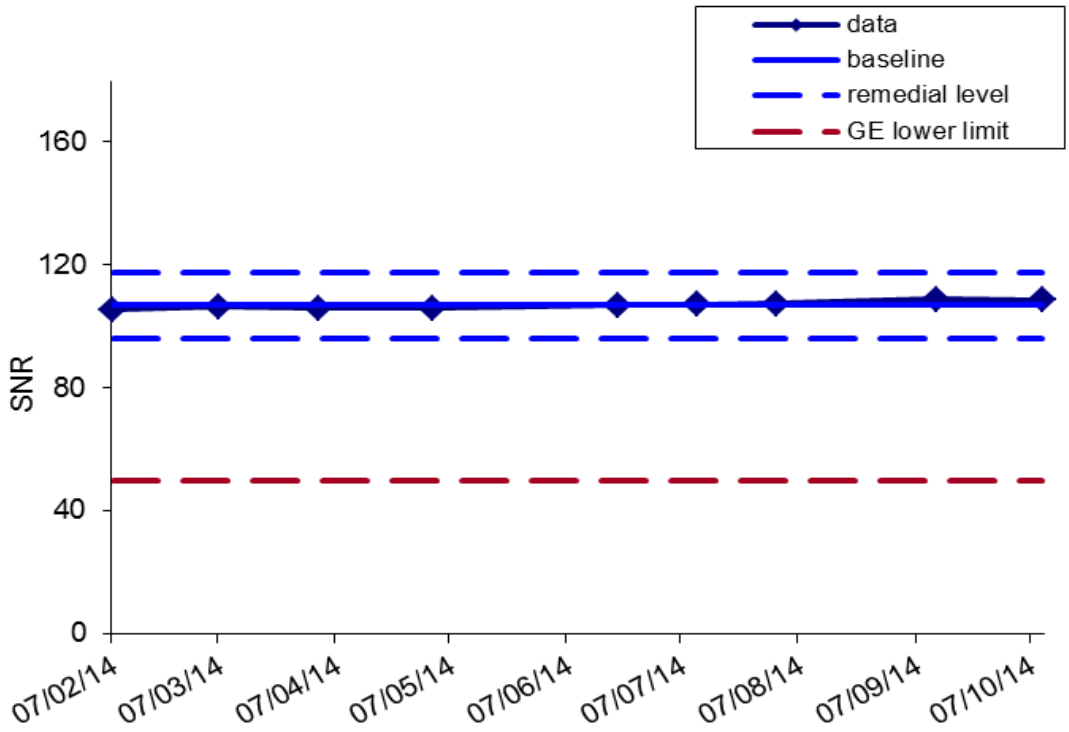

Figure 32. Monthly SNR for 60mm based on GE AOP results at Nottingham (2D)

3.4.2 GE tests – AOP in tomosynthesis

This test is the same as that in Section 3.4.1, except that the exposures are made in tomosynthesis mode and the SNR is not calculated. The NHSBSP QC protocol[11] prescribes monthly checks of SNR and CNR for three different thicknesses of Perspex, if the values can be measured at the AWS. This is not possible with the SenoClaire.

Table 3. Exposure parameters recorded and GE action limits for tomosynthesis exposure

Perspex thickness (mm)	Exposure parameters		GE action limits		
	Derby	Nottingham	kV	Target / filter	mAs
25	n/a	26kV Mo / Mo	26	Mo / Mo	20-70
50	n/a	29kV Rh / Rh	29	Rh / Rh	40-90
60	n/a	31kV Rh / Rh	30 or 31	Rh / Rh	50-120

The mAs values for Nottingham are shown in Figures 33 to 35; the results are within the GE limits and within the NHSBSP remedial limits of ±10%. No results were available for Derby.

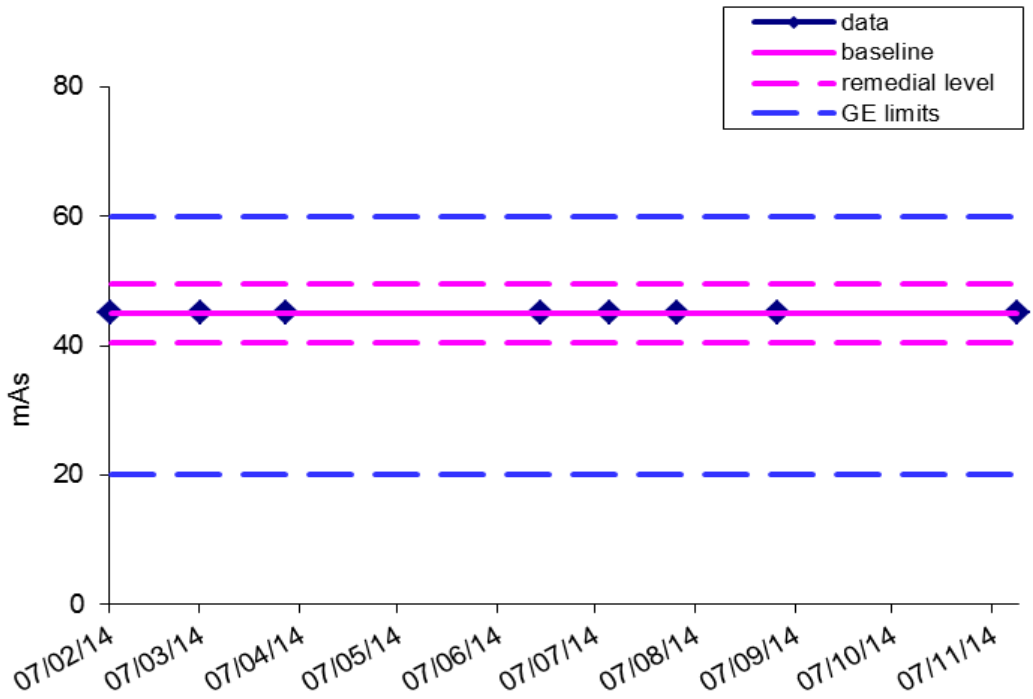

Figure 33. Monthly mAs for 25mm based on GE AOP results at Nottingham (tomosynthesis)

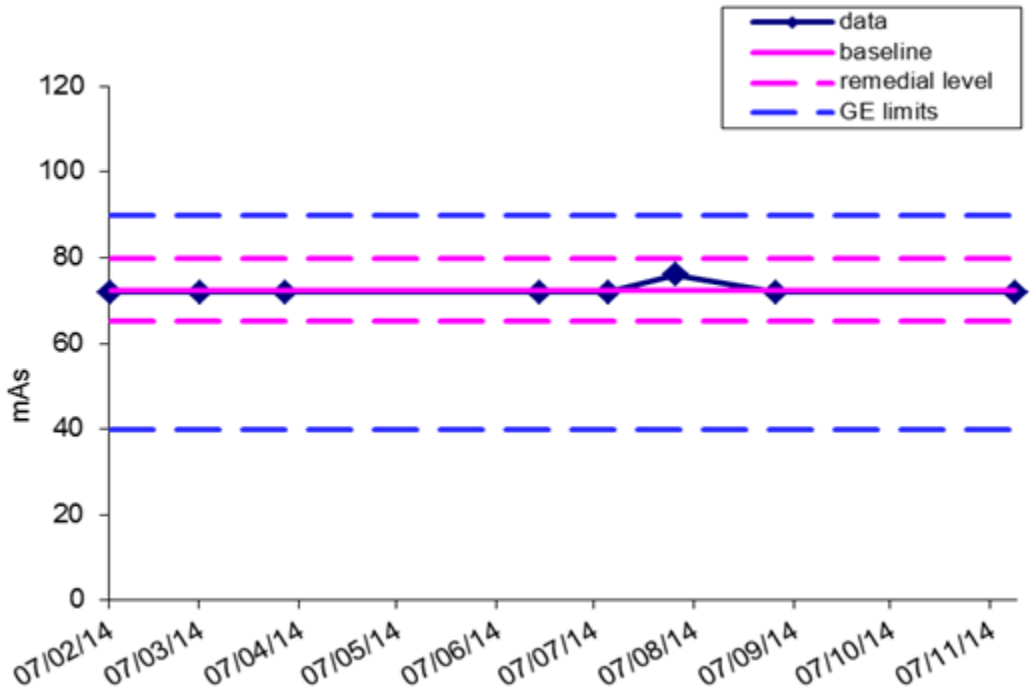

Figure 34. Monthly mAs for 50mm based on GE AOP results at Nottingham (tomosynthesis)

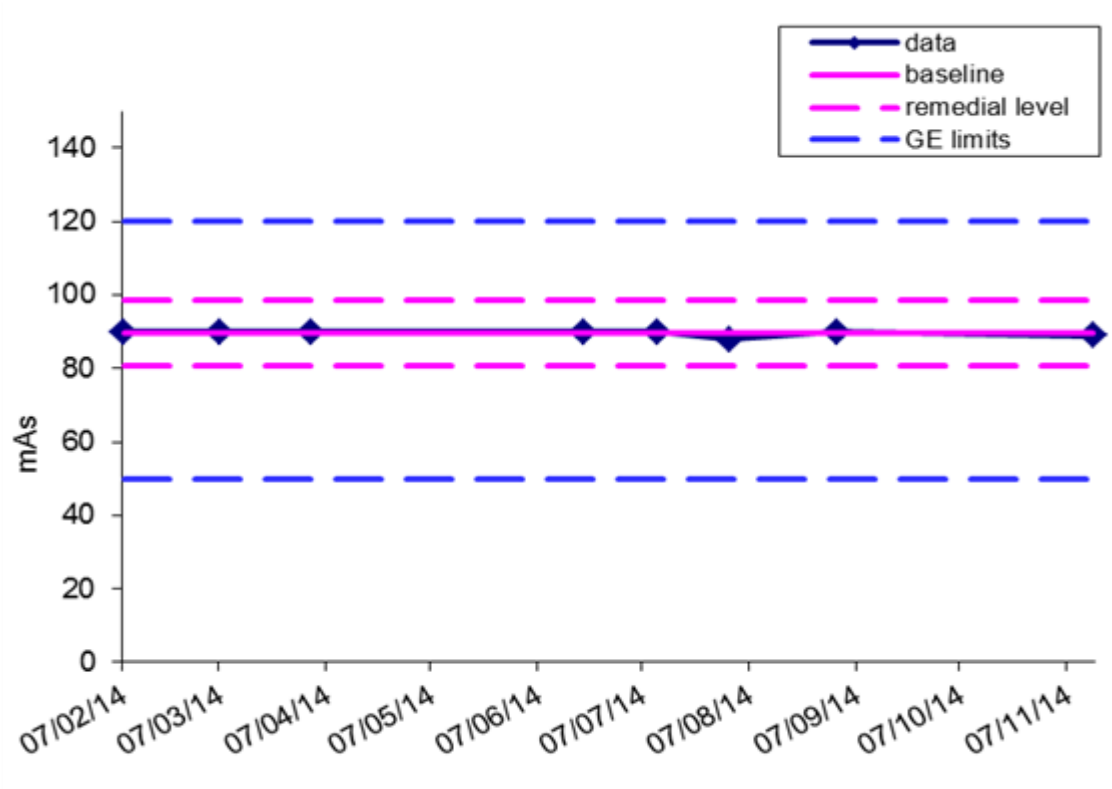

Figure 35. Monthly mAs for 60mm based on GE AOP results at Nottingham (tomosynthesis)

4. Data on assessments conducted

4.1 Clinical Dose Audit

For the purposes of the research trial, only the affected breast was imaged, normally with both a cranio-caudal (CC) and medio-lateral oblique (MLO) tomosynthesis projection. There were no 2D exposures acquired in combination with the tomosynthesis exposure.

The exposure data from 160 women imaged in Derby and 162 women imaged in Nottingham were recorded. This data was entered into a modified version of the NHSBSP dose calculation database. The doses were analysed independently for the two participating centres.

The detailed results of the dose survey, for Derby and Nottingham respectively, are presented in Appendix 2. The average mean glandular dose (MGD) and compressed breast thickness (CBT) are summarised in Tables 4 and 5 below. MGDs were calculated using data published by Dance at al.[13,14]

Table 4. Average values of MGD and CBT for Derby

View	Group of women	Average MGD (mGy) for tomosynthesis	Average CBT (mm)
CC	all	1.53	57
MLO	all	1.68	59
MLO	CBT 50-60mm	1.50	55

Table 5. Average values of MGD and CBT for Nottingham

View	Group of women	Average MGD (mGy) for tomosynthesis	Average CBT (mm)
CC	all	1.60	60
MLO	all	1.77	61
MLO	CBT 50-60mm	1.51	56

The national diagnostic reference level (DRL) for mammography is 3.5mGy for an MLO view of a 55mm compressed breast. There are currently no limiting values for tomosynthesis but this national DRL figure for 2D exposures may be used for comparison. The dose survey results for the GE Essential SenoClaire tomosynthesis systems at both Derby and Nottingham are well below the national DRL.

The most recent dose audits for 2D imaging for both these systems found that the average MGD for 50-60mm breasts was 1.43mGy for Derby and 1.14mGy for Nottingham. The tomosynthesis exposures are therefore approximately 5% higher than 2D in Derby and 32% higher than 2D in Nottingham. Whilst the 2D dose audit data was not obtained from women who were involved in the tomosynthesis study, the calculated doses compare favourably with data from other manufacturers' systems.

4.2 Comparison of displayed dose with calculated MGD

The calculated MGDs were compared with the doses which are displayed on the acquisition workstation and which are stored in the organ dose field of the DICOM header. The displayed doses are plotted against the calculated MGD for Derby data in Figure 36 and for Nottingham in Figure 37.

Displayed doses are calculated according to the method proposed by Wu et al.[15,16] The calculated MGDs have been calculated using data published by Dance et al.[13,14]

The trend lines plotted through the origin indicate gradients of 1.08 and 1.14 for the Derby and Nottingham systems respectively.

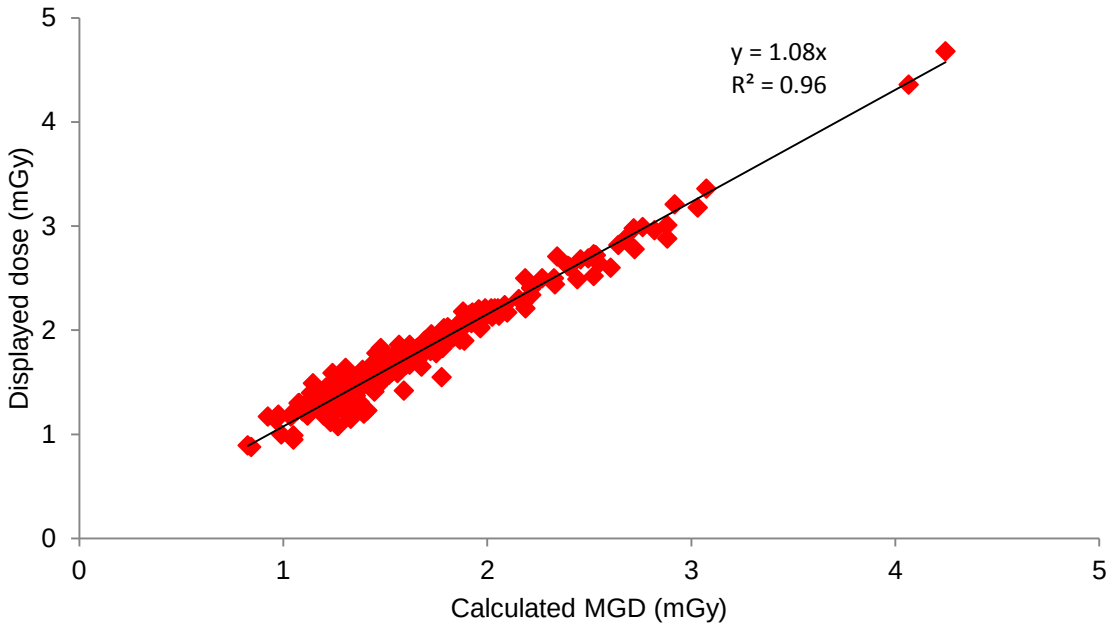

Figure 36. Displayed dose against calculated MGD for Derby

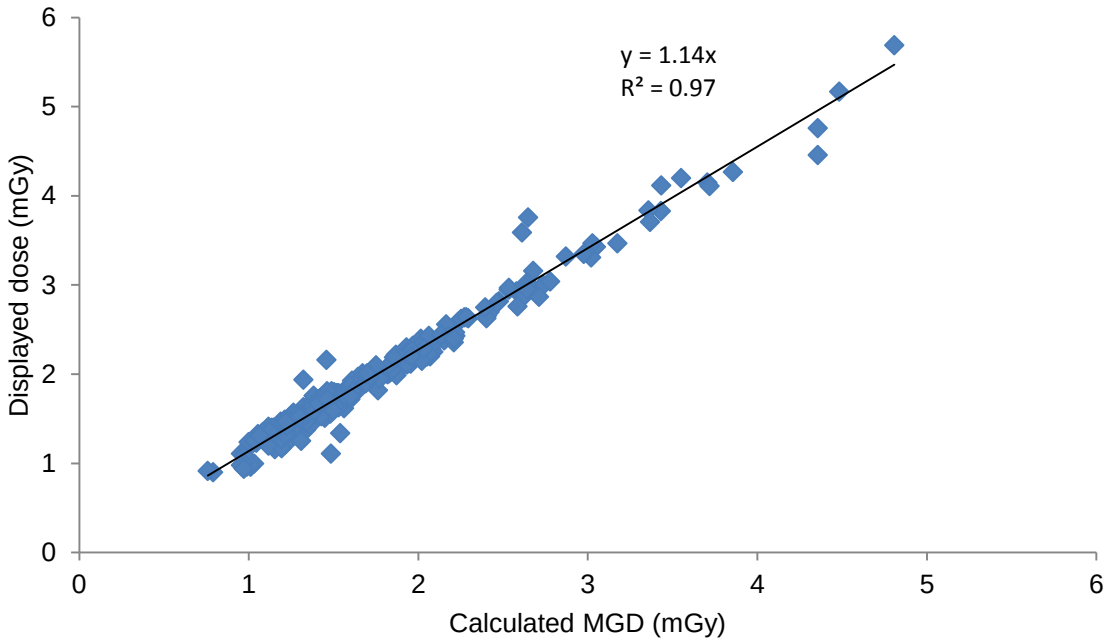

Figure 37. Displayed dose against calculated MGD for Nottingham

4.3 Breast Density

Breast density information obtained from 61 consecutive cases taken near the end of the clinical trial period was reviewed for the purposes of this evaluation.

The readers were asked to make an estimate of the percentage breast density for each case within the dataset collected. These cases have been classified as fatty (0-33%), mixed (34-66%) and dense (67-100%). The proportions found in the 61 cases considered were:

- Fatty: 33%
- Mixed: 62%
- Dense:5%

The results are shown in Figure 38 below.

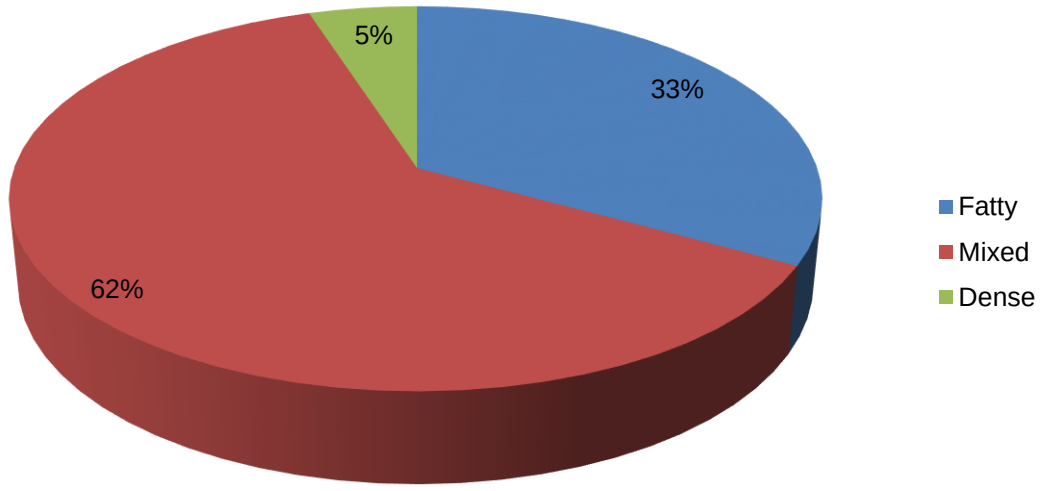

Figure 38. Reader estimates of breast density

4.4 Imaging times

The complete assessment times for each woman are not reported here, as the research trial[2] included the process of consenting and answering any questions each woman had.

The timings for image acquisition and for exposures of a phantom were measured with a stopwatch to determine how long each step of the tomosynthesis acquisition process took. These included start of exposure, first image to appear on the monitor, end of exposure and last image to appear. The timing was repeated ten times and was found to be consistent. The same timings were also taken in 2D mode, again giving consistent outcomes.

The results of the timings are shown in Table 6 below. All timings were from when the operator pressed the exposure button, and are cumulative. The time when the compression is released is indicated by (R).

During the clinical trial a two-view tomosynthesis exposure was acquired, of only the breast being assessed. There were no cases where a combination of 2D standard mammography and tomosynthesis was performed. The timing for this combination, therefore, could not be measured.

The time taken between the beginning of one acquisition and the start time of the next acquisition was identified from the DICOM headers. This time includes the repositioning of the woman, and moving the tube head from CC to oblique position. The average time for a two-view tomosynthesis image, from the beginning of the first exposure was 96 seconds. A synthetic 2D image was also produced automatically as part of each tomosynthesis exposure, with no additional time required.

Clearly the final arbiter for the total time taken for two views for each woman is the time required for positioning the woman.

Table 6. Stopwatch timings in seconds for exposures of a 45mm Perspex phantom

Type of exposure	Time for tomosynthesis mode in seconds	Time for 2D mode in seconds
Start of exposure	2	2
First image appears on screen	8	9
End of exposure	13 (R)	8 (R)
Last tomosynthesis image appears on screen	18	-
Unit ready for next exposure (cycle time)	23	14

4.5 Timings for image reading by radiologists

A total of eight consultant radiologists, five at one centre and three at the other, read the tomosynthesis images.

In Derby, the IDI review workstation used for reading tomosynthesis images was located centrally within the clinical area, between the two mammography rooms and adjacent to the two ultrasound rooms. Each of the two radiologists present in the clinic had a fully integrated GE PACS workstation with access to both NBSS and CRIS in either of the ultrasound rooms. The initial screening mammogram, the priors and additional views were reviewed in the ultrasound room. The radiologists then reviewed the tomosynthesis image on the IDI workstation. The complete tomosynthesis image series was also accessible from the IDI workstation. If a lesion was seen, the relevant images were selected using either the mouse or dedicated keypad. Measurements were made and screen shots were taken and sent to PACS.

In Nottingham, the IDI review workstation was positioned in the clinic review area to enable the image readers to access all images from the woman during the assessment session. This allowed the tomosynthesis images to be read at the same time as the screening images. The radiologists reported each case as it became available and manipulated the images and display settings on an individual case basis.

Once the tomosynthesis images were available on the IDI workstation, switching between the 2D, spot compression views and tomosynthesis images was rapid. The time taken to review each case varied according to the complexity of the case. An informal discussion with the radiologists revealed that the total reviewing time was between five and ten minutes per woman, including reviewing the case with the other radiologist present in clinic.

In both Derby and Nottingham, the IDI workstations were only used in the assessment of women having tomosynthesis, either as part of the clinical trial or within the symptomatic service, according to local protocols. Both centres already had different systems in place for all other mammography film reading tasks, which meant that the radiologists had limited experience in using the IDI workstation. Despite this, the majority of radiologists found the IDI workstations straightforward to use. The IDI workstations with their specific keypads have been successfully used for screen reading within the NHSBSP for many years.

4.6 Clinic workflow

The clinical trial at both evaluation centres required that the women be consented. This added extra time to the running of the clinics as the time taken for consent of each woman was approximately 15 minutes. The consent was taken in a clinic room within the main assessment/clinical area.

In both evaluation centres the additional views were acquired in a different room. Local practice in how the equipment was used was different at the two sites.

In Derby the MTD was left in place in one of the two digital mammography rooms. Any additional standard compression or other views were performed in the adjacent mammography room. Stereo core procedures were begun mid-morning once all tomosynthesis images had been acquired, with the MTD removed and the stereo unit in place. Once all additional images were complete, both rooms were used for stereo procedures.

In Nottingham the MTD was not left in place as the system was also used for routine screening. The Nottingham stereo equipment is an add-on to a separate mammography system. The use of tomosynthesis did not, therefore, impact on the use of the stereo equipment.

4.7 Visibility and additional diagnostic value with tomosynthesis

For the clinical trial, women were eligible for recruitment if they had been recalled for further assessment, following routine mammographic screening within the NHSBSP for a soft tissue abnormality of any type. Women principally recalled for a clinical reason or for calcifications were not recruited. Previous work[17-21] demonstrates the role of tomosynthesis in the assessment of various features but not including calcifications. The majority of research has been performed using the Hologic tomosynthesis system, although similar results were found by Noroozian et al.[22] This study used a prototype GE tomosynthesis system.

An evaluation of the Hologic system[23] found no difference between 2D and tomosynthesis in the detection of calcifications. In this study, patients in whom calcification was the predominant mammographic feature were not assessed with tomosynthesis. There was, however, a small group of patients for whom calcification was documented as an associated feature. These 14 cases were retrospectively reviewed. In eight cases visualisation of calcification with tomosynthesis was equivalent to 2D imaging. In five cases, the calcification was visualised adequately but less well than with 2D imaging. In one case, the associated calcification was not clearly visualised with tomosynthesis. Use of slabs improved the visualisation of calcification in the majority of cases.

A subset of data from 61 consecutive women out of the 322 women who took part in the clinical trial was selected for further analysis in this evaluation. The protocol for the clinical trial is different to that of the TOMMY study.[18] This dataset was smaller than the data used in the Hologic digital breast tomosynthesis NHSBSP evaluation.[23] As a result, data regarding visibility and diagnostic value are discussed together, with only the latter presented in graphical form.

The readers were asked to assess the conspicuity of any feature, on each view, for each modality. They were also asked to make a further decision as to whether tomosynthesis had been of any additional help with diagnosis or not. Their responses were chosen from the following categories: “no additional help”, “had been a useful aid to diagnosis” or “had aided diagnosis”. The options that could be selected for how tomosynthesis might have aided diagnosis included “margin characteristics”, “extent”, “multi-focality” or “other” reasons.

A review of the 61 cases showed that 25 of 61 (41%) had no significant abnormality at assessment. In a high proportion of these cases, including 11 of 15 asymmetrical densities (ASD), and three of four possible distortions, tomosynthesis was considered to have had a significant role. It was a useful aid to diagnosis by providing additional imaging which clearly demonstrated a normal appearance and added confidence to the assessment.

In the remaining group there were 37 abnormalities in 36 cases. 16 of these were malignant lesions found in 15 women, with one case of DCIS which only appeared as a well-defined mass (WDM). One case showed two spiculate masses. Both of these masses were seen equally well on 2D additional views and tomosynthesis.

For the cases with a WDM, in five of the 24 cases (21%), readers felt conspicuity was better with tomosynthesis than standard views. In one of these five cases, the abnormality was clearly seen with tomosynthesis to be a well-defined mass and not an asymmetrical density as was initially thought. This helped ensure correlation with the subsequent benign cyst found on ultrasound. In eight of the 24 cases (33%), the readers felt tomosynthesis had been a useful aid in diagnosis by principally reporting improved visualisation of the margin of the lesions. In two cases, the readers reported tomosynthesis had definitely aided diagnosis. Both clearly showed the location of a lesion within the breast, whereas on standard 2D views, the abnormality was only seen well on one view.

Seven of the eight spiculate masses found in seven women were considered to be well visualised initially on both modalities. In the last case, a tiny lesion was thought to lie in the upper, inner breast on standard additional views, but tomosynthesis then clearly added value by showing that the lesion was in the upper, outer breast. The radiologists also reported that there was added value from tomosynthesis in more than half the cases, as it gave a better assessment of lesion size and margin.

In the remaining four asymmetrical densities and six possible parenchymal distortions, readers reported tomosynthesis to be a useful aid in more than 50% of cases. In particular, it helped reinforce diagnostic confidence when no abnormality was present. This ability of tomosynthesis to show that a possible soft tissue density simply

represents normal, superimposed tissue has already been previously described[17,18]. In addition, in two cases, one an asymmetric density and the other a parenchymal distortion, tomosynthesis was felt to have significantly aided diagnosis in the margin assessment and in the extent of the abnormality, respectively. Both these lesions were invasive lobular cancers.

The data demonstrates that GE digital breast tomosynthesis is at least equivalent to standard supplementary mammographic views when used in the assessment clinic for the diagnosis of screen-detected soft tissue breast lesions. Dose levels are satisfactory and compare well with those of other manufacturers.

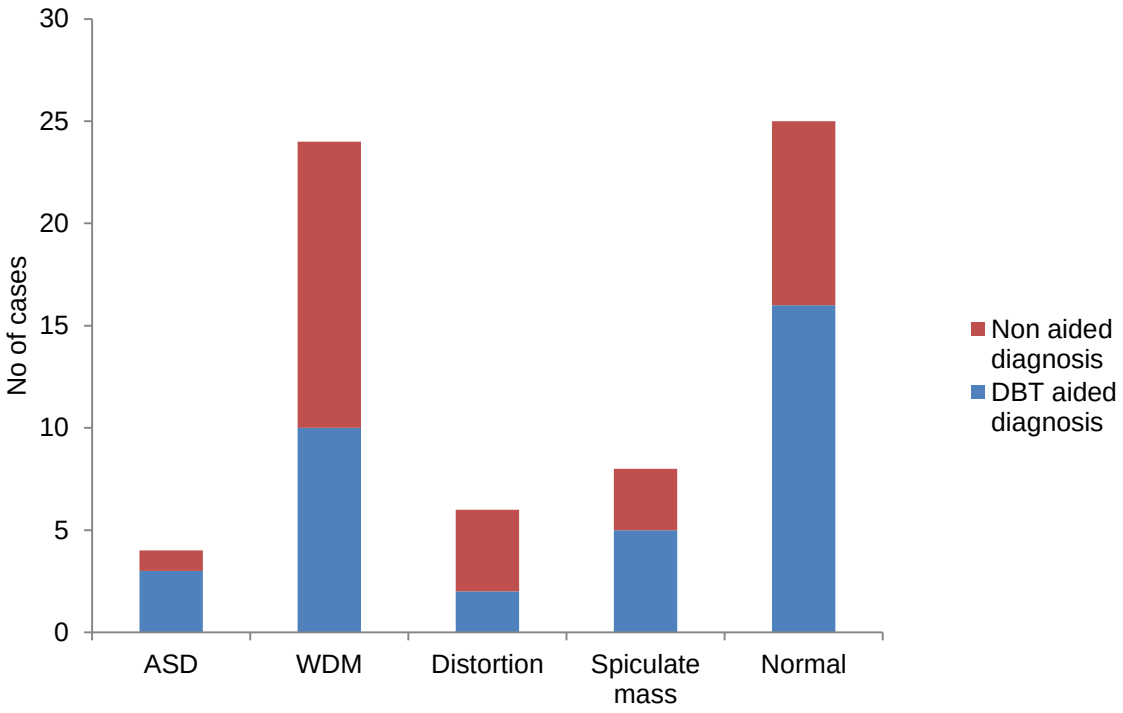

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Figure 39. Added diagnostic value of tomosynthesis compared to standard 2D mammography

The stacked column chart in Figure 39 categorises where tomosynthesis was felt to have significantly added value in diagnosis. The added value across all possible features assessed is 54.5% in this sample of 61 cases. This matches closely with the figure of 56.9% found in the analysis of all 322 cases in the clinical study. The radiologists also commented that tomosynthesis is particularly helpful in the delineation of where the margins are in the lesions and in the confirmation of benign/normal appearances at assessment.

4.8 Image transfer time from PACS to the IDI workstation in Derby

At the Derby site, it was observed that there was a time delay for the full file of tomosynthesis images to reach the IDI workstation and be available for interpretation and viewing. This time varied typically between one and two minutes but would occasionally rise to eight minutes. With similar delays being reported in the main imaging department when viewing a range of images, it was recommended that a review of the image transfer time be carried out when the trust upgraded its PACS.

The upgrade took place after the period of evaluation in early 2015. It resulted in better image transfer times as confirmed by a small formal audit which showed more satisfactory times when using tomosynthesis in a busy clinic. Transfer times were typically reduced to 41 seconds during busy periods and increasing to two minutes and 9 seconds for very large file sizes.

4.9 Assessment of 2D mammograms acquired with MTD

Twenty-five routine mammograms acquired with the MTD in place were reviewed independently by four readers to assess their diagnostic quality. Overall, 20 of these mammograms were assessed as excellent image quality and five as good image quality. None were categorised as average, poor or very poor. The readers subsequently commented that they were unable to identify any difference between cases imaged with the MTD in place and those imaged with the standard 2D Bucky.

The radiographers' comments regarding performing a 2D mammogram with the MTD in place were that it is almost exactly the same to use as in the normal 2D configuration. There is a slight reduction in the space between the detector and the compression plate when positioning the breast. This is only noticeable when performing a mammogram on large breasts, using the 24cm x 31cm paddle.

5. Equipment reliability

During the evaluation, assessment clinics were run on one day each week at each of the two sites in Derby and Nottingham. The equipment was generally reliable throughout that period.

There were no faults reported at the Derby site. Two faults were reported at the Nottingham site on the NHSBSP Equipment Fault Report Forms with a total downtime of half a day.

The first fault was in April 2014 when the detector became very warm after an equipment service, leading to higher SNR measurements. This was resolved when the detector cooled down.

The second fault occurred in June 2014 when the tomosynthesis attachment would not load on to the GE Essential. Following an engineer visit, the fault was diagnosed as a bent pin on the tomosynthesis connector plug. This was straightened and fixed by the engineer.

Both faults are recorded at Appendix 4.

No further issues were reported at either site during the rest of the evaluation period.

6. Electrical and mechanical robustness

There were no safety issues, and no electrical or mechanical problems were encountered during the evaluation period, other than the two faults reported in Section 5.

The handling and lifting of the MTD in order to connect it to the GE Essential was resolved by the provision of the mobile cart shown in Figure 4. The positive effect of the mobile cart is also mentioned in the radiographers' comments in Section 7.

7. Radiographers' comments and observations

Standard evaluation form 11 from the NHSBSP evaluation guidelines[1] was used to collect the views of radiographers regarding the use of tomosynthesis for assessment in this evaluation. A total of 11 questionnaires were returned, from staff at both sites. The responses are amalgamated in the table at Appendix 5 and the main points are explained below.

During the assessment clinics at both sites, the MTD was installed on the existing GE Essential system. This meant that the equipment could not be used for additional views at the same time, although 2D standard mammograms could be acquired using the MTD. Also, because use of the equipment was part of a research trial, there was an additional time commitment related to consenting and explanation to women. While this did not relate to the practical use of the tomosynthesis system, it contributed to the radiographers' overall experience and to the practicality of the work flow in assessment.

7.1 Operator's manual

GE provided an operator manual two weeks after the upgrade to tomosynthesis had been installed and application training had been given. Just under half (5) of the respondents considered the manual as good and the same as a 2D imaging manual, while the others had neither used nor seen the manual.

Two of the respondents would have liked an in-house simplified version, which is something that could be written locally. One respondent found it useful to have the full version for reference.

7.2 Training

GE delivered the applications training for tomosynthesis to all the senior radiographers who were required to use the equipment.

The clinical application training provided by GE for the modality was rated as excellent (1), good (8) and average (2), by the respondents. They all considered it to be the same as for 2D imaging.

The training for the acquisition workstation was considered to be excellent (1), good (4) or average (3) by most of the respondents and satisfactory (3) by the remainder. Six of the respondents reported it to be the same as for 2D imaging.

Two respondents commented that the training felt rather rushed; this was, however, due to clinical pressures on staff in other areas. It was also commented that training for image reconstruction from PACS was not given to all individuals, but only to senior staff.

7.3 Ease of use of system

The ease of use was rated as good (10) or average (1) by all of the respondents. The addition of tomosynthesis capability to an existing piece of known equipment will have assisted with this.

7.4 Ease of attachment and removal of the MTD

Respondents rated this as excellent (1), good (4) or average (2) and a minority rated this as only satisfactory (2) or poor (2). One radiographer changed their response from poor to excellent after the introduction and use of the cart, which was not available at the beginning of the evaluation.

Generally, the MTD was considered too heavy to be manually lifted on and off, and this was commented on by five of the radiographers. The weight and bulkiness of the MTD made it difficult to attach or put on the resting platform, causing manual handling issues. However, with the availability of the cart, attachment and removal became easy with no lifting required on the part of the operator.

7.5 QA tests for tomosynthesis

Nine of the respondents found the QA tests straightforward to perform. One found them easy, one found them difficult and one commented that there were many tests. Two commented that they had not been shown the QA tests but had done them with assistance, or worked them out for themselves.

The response to the calibration tests question was similar to that of the QA test, with most (9) finding them straightforward (9), one easy and one unaware of the tests. The senior staff and those leading in QA were satisfied with their training to perform the QA tests, and could assist others as needed.

Additional documentation for the QA testing of tomosynthesis systems became available towards the end of the period of evaluation.

7.6 Compression times for tomosynthesis

Compression times were generally thought to be acceptable by most (10) of the respondents, although one did not indicate either way since they had not had any feedback from any of the women. When compared with the 2D imaging, the compression was considered the same (5) or slightly longer (5). Generally, the time of compression were remarked on by radiographers as slightly longer than for the 2D imaging, but this was not commented on by the women.

7.7 Limit to patient throughput for tomosynthesis

Throughput of women was not indicated as being limited by the majority of respondents (7), who also thought it was the same as for 2D imaging. The other four felt that it did limit the throughput of women.

Four radiographers mentioned that a spot compression paddle, not an option at present, would have been useful. This would have removed the need to remove and reattach equipment between women during the assessment process. However, if tomosynthesis is used routinely for assessment in the future, a spot compression paddle would rarely be needed.

7.8 Comfort level for the women for tomosynthesis

The majority of respondents said the women's comfort was good (6) or average (4), with only one reporting it as satisfactory. One radiographer reported that it could be difficult when positioning the woman's head, while another thought that with the longer exposure time, some women were finding it difficult to remain in the oblique position for so long. Another stated it to be similar to 2D imaging.

Other radiographers stated that when positioning they needed to make sure the woman held on to the correct handle for the oblique views, in order to ensure a good quality image. Another reported that they always informed the woman that the gantry face panel moved and no problems seemed to occur.

Overall the radiographers had not received any feedback from the women that they found the tomosynthesis any more difficult than normal 2D imaging.

7.9 Range of controls and indicators for tomosynthesis

All the expected controls were present and the respondents all said that they were easy to find and use, being similar to those for 2D imaging.

7.10 Image appearing at the AWS and image storage for tomosynthesis

The time taken for the projection images to appear at the AWS was judged as excellent (2), good (3) and average (2), with four rating it as satisfactory.

When compared to 2D imaging, timing was rated to be the same by six of the respondents and slower by five. One respondent commented that the time taken was dependent on the traffic on the PACS, and would take longer if many other images were being acquired. For image storage, most respondents rated the timing as excellent (1), good (3), or average (4), while others considered it to be satisfactory (2) or poor (1).

The time taken for auto-delete was not rated, since radiographers had been instructed not to delete images during the trial.

In view of these comments, the time taken for image transfer from the MTD to the workstation was audited, with the results given in Section 4.8.

7.11 Image handling and processing facilities at the AWS for tomosynthesis

When rating the image handling and processing facilities at the AWS, scrolling through the projection images was rated as good (5), average (3) and poor (1) with two radiographers not having used the scroll facility.

Respondents rated the processing as good (4), average (4) and satisfactory (1), while two stated that they had not used this facility.

The retrieval of images was considered good (4), average (2) or satisfactory (3), with two respondents stating that they had not used this facility. In addition, one respondent stated that the retrieval was slow to use in a busy clinic.

As the formal review of images on the workstation being carried out by radiologists and advanced practitioners, the other radiographers therefore had less familiarity with these facilities of the equipment.

7.12 Ease of use of the controls on the AWS

Use of the controls did not appear to cause any particular problems, with most (8) of the respondents rating the controls as the same as for 2D imaging, with two other respondents making no comment.

The keyboard was rated as excellent (1), good (3) and average (5), with one rating it as satisfactory and one as poor. The scrolling wheel was rated as good (8) and satisfactory (1) while two radiographers indicated that they had not used the scrolling wheel. One respondent commented that it was good for fine control.

7.13 Image quality for tomosynthesis

Image quality was rated across a range of good (3), average (5), satisfactory (2) and poor (1) for the acquisition workstation. Two radiographers commented that the images were grainy and another that they were very grainy, with the image cut off at the bottom of the screen. Two others stated that image quality seemed reasonable, but they had nothing to compare it with.

The overall image quality was again rated across a range as good (2), average (5), satisfactory (3) and poor (1). There were comments that the images appeared grainy, not sharp, with the pixels visible.

It should be noted that these comments refer to the images visible on the AWS. These were not the diagnostic images but simply an image set to assess if the whole breast area had been covered. The full set of processed images could only be seen on the IDI workstation. Projection images are noisy because they are low-dose, as explained in Section 1.2.3.

7.14 Level of confidence in the tomosynthesis system

In general respondents rated their level of confidence in the tomosynthesis system as excellent (1), good (7) or satisfactory (3), with most judging it to be the same (7) rather than worse (1) or better (1) than 2D imaging. However, one radiographer commented that they had found tomosynthesis to be satisfactory but worse than 2D imaging, and preferred another tomosynthesis system that they had trained on in another hospital. They also commented on the images at the AWS being grainy.

7.15 Hazards

Most (8) respondents reported that there were no hazards to the operator due to the operation of the tomosynthesis system and the same number considered that this was the same as for 2D imaging. Three others stated that there were hazards, and that the system was worse than 2D imaging.

The main issue was the manual handling of the MTD when fitting to or removing from the mammography system, although this was overcome with the provision of a cart.

7.16 General comments

Several radiographers gave the same comments on the questionnaire. Generally, respondents thought that tomosynthesis was good, and did not find issues with its use

Some of the frequent comments were

- the MTD was heavy/ bulky when manually handled; this was however overcome with the cart that was provided
- images produced on the AWS were grainy and did not cover the whole area of the breast, with the bottom part of the oblique images missing
- a spot compression paddle for use with 2D imaging on the MTD would have been convenient
- when examining women with larger breasts, the compression paddle does not lift up as high as with standard mammography equipment, so making it difficult to position, with less space vertically even with the elevated paddle in use
- reference to the operator manual is necessary for women with smaller breasts, in order to set manual exposures
- tomosynthesis mode was considered easy to use, provided a little extra time was allowed for explanation to the women

8. Radiologists' comments and observations

Standard evaluation form 12 from the NHSBSP evaluation guidelines[1] was used to collect the views of radiologists concerning the use of tomosynthesis for assessment. Seven out of eight questionnaires were completed and returned. The main points are explained below with the responses amalgamated in the table in Appendix 6.

8.1 Operator manual

Only one of the respondents used the manual, and scored it as good.

8.2 Applications training for tomosynthesis

Training on the workstation was reported as excellent (1), good (3), average (1), satisfactory (1) and poor (1). All the radiologists who responded had attended external training courses for tomosynthesis mammography, five at Kings College Hospital and two at Buc in Paris. The former course is recognised by the NHSBSP while the latter is organised by GE.

8.3 Use of reporting station controls for tomosynthesis

Most of the respondents rated the mouse, keyboard and keypad as good (4), with the rest reporting the controls as excellent (1), average (1) and satisfactory (1). Readers did not find any issues with their use.

8.4 Image handling tools for tomosynthesis

The rating of image handling tools, such as zoom for tomosynthesis, varied widely with responses of excellent (2), good (1), average (3) and poor (1). One radiologist commented that the image manipulation tools were not intuitive; they were poor and difficult to use.

The special tomosynthesis handling tools, such as slider or cine, were rated excellent (2), good (1), average (2) and satisfactory (2). One radiologist (of the seven respondents) noted that both ordinary and special tomosynthesis handling tools were too slow and unresponsive.

8.5 Visibility and usability of on-screen icons for tomosynthesis

The on-screen icons were scored from excellent (2) through good (1), average (2), satisfactory (1) to poor (1). One reader had a problem with the measuring tool, finding it difficult to use, whilst another reader found the IDI workstation not very intuitive. They either needed to be shown how to do everything or had to spend a lot of time searching through the online help.

It should be noted that of the seven radiologists who responded, only one made several comments of this type.

8.6 Slab thickness change when viewing tomosynthesis images

It is not possible to change the slab thickness with the SenoClaire. None of the readers attempted to do so.

8.7 Reading/reporting workflow pattern in tomosynthesis mode

Four respondents rated the workflow as good with another as satisfactory.

8.8 Time for image to appear on screen in tomosynthesis mode

For each new client the time was judged as good (4), average (1) or satisfactory (2), compared to in-examination change where the time was marked as good (6) and satisfactory by one respondent. Comments were made that it felt like a long time when waiting to view a newly acquired tomosynthesis mammogram, and that it was not easy to get to the next client. One reader found it annoying when the message “you have not viewed all the images” appeared.

8.9 Recording findings on NBSS for tomosynthesis images

This function is not yet activated.

8.10 Adjustment of the reporting monitors to suit the user

One respondent found this average; four more had not tried or not needed to make any adjustments.

8.11 Navigating between tomosynthesis slices

Five of the respondents found this easy and two found navigating through slices average.

8.12 Hanging protocols for tomosynthesis

The applications specialist had initially set up hanging protocols. The respondents typically commented that this had been done and they were not involved. One indicated that it was not necessary to change them. Another reader responded that it was easy to change from one hanging protocol to another, but that it is changing the protocols themselves that is difficult. Two found this more difficult.

8.13 Image quality of tomosynthesis images

The majority of respondents considered the image quality to be good (5), with one excellent and one average, for both contrast and sharpness. Two readers commented that the synthetic 2D images seemed poor. It is noted that there is ongoing work by GE regarding these, but they were not part of this evaluation.

8.14 Overall satisfaction in use for assessment

The overall opinion from respondents was that tomosynthesis was excellent (1), good (5) and average (1).

8.15 General comments

Overall the radiologists were very positive regarding the use and value of tomosynthesis in assessment. Only one radiologist (of seven respondents) made several comments that they found the IDI workstation frustrating and difficult to use, but did also comment that tomosynthesis was a very useful tool.

The comments overall included:

- no significant problems
- tomosynthesis is a very useful technique
- the use of tomosynthesis is very helpful in assessment clinics for the assessment of distortions
- synthetic 2D images will need evaluation in the future

9. Information Systems

9.1 Workflow configuration

9.1.1 Derby

In Derby, the GE Essential is connected to the main hospital GE PACS. The images for each woman are all integrated into a single PACS record. For the evaluation, the raw images acquired by the SenoClaire were automatically sent to the GE PACS. The complete diagnostic set of tomosynthesis images, including the raw and processed images and the reconstructed images (slabs and planes), was also automatically sent via the local area network to the IDI workstation for review by the radiologist. Figure 40 shows the image workflow in Derby.

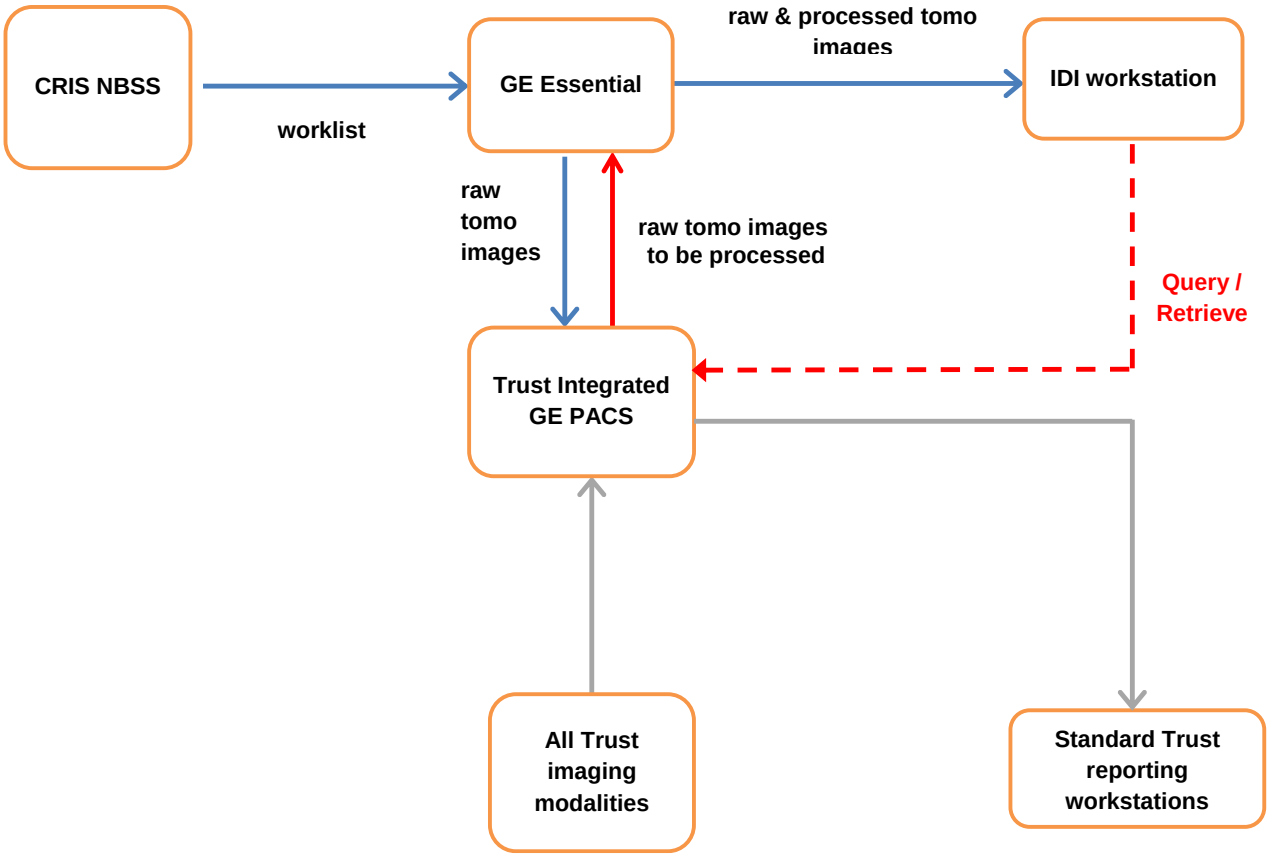

Figure 40. Image workflow in Derby

The IDI workstation is also connected to both the hospital radiology information system (CRIS) and to NBSS. This enabled all prior images to be available using the

query/retrieve facility on the IDI workstation for comparative imaging. Any additional screen shots from the IDI workstation could easily be sent to the PACS with a few mouse clicks. Image manipulation and client selection on the IDI workstation could be performed either by using a mouse or by using a dedicated workflow keypad as shown in Figure 42.

9.1.2 Nottingham

In Nottingham, both the GE Essential and GE IDI workstation are connected to the main hospital Agfa PACS. The GE Essential is also connected to the hospital radiology system, CRIS, enabling the retrieval of client worklists onto the AWS.

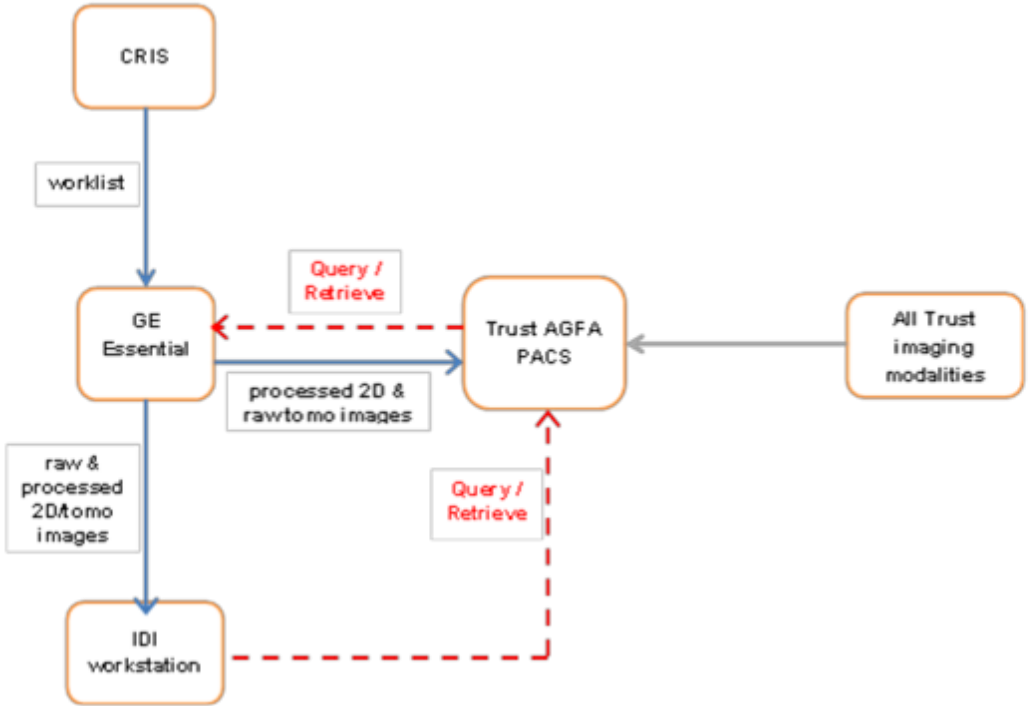

Figure 41. Image workflow in Nottingham

In the evaluation, the raw and processed tomosynthesis volume images acquired on the GE Essential from the examinations were automatically pushed to the IDI reporting workstation. This allowed the reconstructed images (planes and slabs) to be reviewed by a radiologist. The prior images of women already stored on PACS could be retrieved onto the IDI workstation for comparative review. Figure 41 shows the image workflow in Nottingham.

The raw tomosynthesis images were automatically pushed to the Agfa PACS system enabling later retrieval onto the AWS of the GE Essential. An additional radiographer task was manual reconstruction of images into volumes on the AWS, which were then pushed to the IDI workstation for review.

9.2 The IDI workstation

The IDI workstation includes a computer where images are cached on the local hard drive, with two Barco Coronis MDMG-5121 5MP displays and a dedicated mammography workflow keypad. There are two keypads currently available for the newer version with more options for customisation.

Figure 42. IDI workstation and keypads

In both centres, prior images could be retrieved from the main PACS to the IDI workstations to allow comparison of current and previous imaging.

Figure 42 shows the IDI reporting workstation and keypads.

9.3 Image sizes

2D images for clinical use vary in size, depending on format. 19cm x 23cm images are 8MB and 24cm x 31cm images are 14MB.

The tomosynthesis images are in the DICOM Standard BTO format and comprise reconstructed planes and slabs. The sizes of these vary depending on the breast thickness and density. There is currently no definition of an “average breast” for comparing tomosynthesis file sizes. For this evaluation, an average breast is a 50mm compressed breast thickness with 75% detector coverage. Table 7 shows the average file sizes for tomosynthesis images.

Table 7. Average file sizes of tomosynthesis images

Image type	Image size (MB) two-view single breast	Image size (MB) two-view both breasts
single raw tomosynthesis image	131	260
complete tomosynthesis series including raw projections, slabs and planes	800	1600

A small audit was carried out to determine file sizes for different breast thicknesses. The sizes were determined in 2015 after the evaluation period, when a new GE PACS was installed in Derby and whole image series saved to it routinely. The results of this audit is shown in Table 8.

Table 8. Audit of file sizes

CBT (mm)	Image type	Image size for 2-view single breast (MB)	Image size for 2-view both breasts (MB)
25	single raw tomosynthesis image	58	120
25	complete tomosynthesis series including raw projections, slabs and planes	180	360
85	single raw tomosynthesis image	370	-
85	complete tomosynthesis series including raw projections, slabs and planes	990	1980

10. Confidentiality and security issues

The evaluation complied fully with the NHS cancer screening programmes confidentiality and disclosure policy.[24] In addition, all the women were participating in a clinical trial, for which they had given their written consent to the use of the data.

The raw images were stored on PACS in each of the two trusts. Assessment paperwork and electronic records were held within the filing system at each site and in NBSS. Access to these was only by breast unit personnel and by authorised users with username and password.

Access to the IDI workstation is by typing a username and password. The software on the workstation was not used to record any reports.

11. Training

11.1 Radiographer training

The training of staff on the tomosynthesis system was provided by a GE application specialist shortly after the time of installation. Staff schedules were rearranged to ensure all radiographers would benefit from this training. They were already familiar with the GE Essential and the training was straightforward.

At both the Derby and Nottingham sites, radiographers involved in the assessment clinics were split into small groups of two or three for training from the application specialist. The application specialist was available for a week on each site prior to beginning the trial period and was also on hand for the first assessment clinic at each centre to resolve any problems.

11.2 Radiologist training

All the radiologists attended tomosynthesis training courses prior to the installation of the equipment. Most of them attended the training at King’s College Hospital, London, while the others went to the GE mammography facility at Buc, south of Paris. The course content from both included: the principles of tomosynthesis, tomosynthesis

appearance of normal, benign and malignant cases, hands-on reading of test cases with a practical self-assessment test set and feedback. The former course is NHSBSP approved.

Applications training for the radiologists was also provided by a GE applications specialist prior to the start of the clinical trial. Each radiologist received individual training on the IDI workstation. At both sites, the trainer was also available in the assessment clinic when the trial began, as discussed in the previous section.

12. Discussion

12.1 Equipment and practical considerations

As part of the upgrade of a GE Essential to tomosynthesis functionality, an MTD is physically attached in place of the standard 2D Bucky. Radiographers found this heavy and difficult to attach and remove at first, but the problem was completely resolved by the provision of a suitable cart. Standard 2D views can be acquired with the MTD in place; the technical evaluation[5] indicates that these would have similar image quality but on average 15% higher dose than images acquired with the standard Bucky. Spot paddles cannot be used with the MTD, so it would have to be removed if additional views were required. This evaluation indicates that tomosynthesis might be able to replace additional views in future.

The stop-and-shoot motion of the tubehead during tomosynthesis exposures did not cause any issues for the radiographers or the women. Exposure times were longer for tomosynthesis than for 2D imaging (13s compared with 8s) but although this was sometimes noticed it was not considered to be a problem.

Automatic acquisition of a tomosynthesis image and a 2D image in the same compression is not possible with the SenoClaire system. This is by design, with the expectation that in future a synthetic 2D image will take the place of a 2D image, with lower dose to the woman. The SenoClaire synthetic images were not evaluated during this evaluation or the clinical trial, and there are no suitable physics tests yet for evaluating them. One radiologist in this study volunteered a comment on the synthetic images, which was negative. If a 2D image in the same compression is wanted, it can be achieved by disabling automatic decompression after tomosynthesis. The operator

then goes from the AWS to the MTD to press the 3D button before taking the 2D image and then releasing compression.

The performance of SenoClaire systems at both sites was very reliable. No faults were reported at Derby while only two minor faults were reported at Nottingham. These were easily resolved.

12.2 Physics testing and routine QC tests

Physics tests carried out at commissioning of the tomosynthesis facility found equipment performance at both sites to be satisfactory. Both tomosynthesis and 2D imaging modes were tested. Six-monthly tests, carried out during the evaluation period, showed that performance remained satisfactory. The IDI workstations were tested and found to meet the appropriate standards.

The physics service also provided the results of dose surveys. The average MGD for MLO tomosynthesis exposures of 50-60mm thick breasts was 1.5mGy at both sites. This is comparable with doses for 2D images, and well within the diagnostic reference level of 3.5mGy for 2D imaging.

There were a large number of QC tests to be carried out routinely, and extensive results are presented in Section 3 and Appendix 3. Staff at Nottingham carried out all the tests recommended by GE. For some tests the software provided numerical results and compared them with limits set by GE. Most but not all of the tests were carried out at Derby, possibly due to training issues. The GE QAP tests are mostly equivalent to the tests prescribed in the NHSBSP protocols for 2D and tomosynthesis tests[7, 11]. A daily test of the AEC with a 45mm block of Perspex was not included, and this was added to the testing regime. The monthly tests with Perspex blocks of different thickness did not include measurement of SNR in tomosynthesis mode or CNR in either mode. These tests are optional in the NHSBSP protocol.

Some GE tests are additional to NHSBSP requirements, and these are included in Appendix 3. The monthly grid texture test was particularly helpful in identifying an upward trend in texture. This was resolved by recalibration before the remedial limit was reached. The brightness and SNR non-uniformity tests provide better information on uniformity than the NHSBSP test, which only measures at the centre and corners of the image. Image quality can be checked with either the TORMAM or the ACR phantom, but both are not required as they provide similar information. Taken as a whole, the extensive test results showed consistent performance in both 2D and tomosynthesis modes. The results were within the NHSBSP and GE limits.

Apart from the large number of QC tests, one practical difficulty was noted. Measurement of some quantities could only be carried out at the reporting workstations, not at the AWS. It was difficult for the radiographers to find time for this in busy screening centres where the workstations were in constant use.

12.3 Clinical assessment

A small, consecutive sample of 61 cases (out of 322 enrolled in the clinical trial) was analysed for this evaluation. Radiologists assessed whether tomosynthesis had or had not aided diagnosis, compared with standard additional mammographic views. Further details are given in the published paper.[2] The results agreed with other published evidence, although this related to different manufacturers' systems. They demonstrated that tomosynthesis can improve visibility of lesions and may be a useful or very useful aid to diagnosis. The particular areas highlighted in this small group included additional diagnostic confidence when no abnormality is present and improved margin assessment. In a small number of cases there was better localisation of the site of a lesion within the breast. Since the end of the study period, several radiologists have commented that they missed the helpful input of tomosynthesis to the assessment process.

In the trial, tomosynthesis was only used for one day a week. When approved for use in assessment, it is likely to be in more frequent use and it would be convenient to keep the MTD permanently in place. Four readers independently reviewed 25 symptomatic 2D mammograms acquired with the MTD. They judged the image quality to be excellent (80%) or good (20%). As the dose is only 15% higher on average, use of the MTD for 2D imaging would seem to be convenient and acceptable.

12.4 Radiographers' and radiologists' views

Radiographers and radiologists were generally satisfied with the training they received and with use of the tomosynthesis system. Only a small number of individuals expressed negative comments or noted difficulties they had experienced. Prior experience with the GE Essential in 2D mode was an advantage to the radiographers in learning how to use the tomosynthesis system. Equally, familiarity with the IDI workstation might have proved helpful to any radiologist who found its use difficult initially for reviewing tomosynthesis images.

12.5 Image transfer and storage

There were a few comments on the time taken for tomosynthesis images to appear at the IDI workstation. At Derby, this was typically 1-2 minutes, but occasionally up to eight minutes. The time is mainly determined by PACS and network issues, not by the

SenoClaire system. After a PACS upgrade in 2015, these times were reduced to 40 seconds typically, with a maximum of two minutes. It is important when installing tomosynthesis systems that network capacity and PACS storage are sufficient, because the images are very large (up to 1000MB).

The tomosynthesis image sizes are similar to those of other manufacturers. Image storage of tomosynthesis studies will have a major impact on PACS. It will require careful management and planning when tomosynthesis is regularly used. The increase in storage capacity is a subject of major importance for the introduction of tomosynthesis. Storing only the raw images for subsequent reconstruction, as required, would reduce the large amount of storage that would otherwise be necessary. This would only be workable if the same or compatible reconstruction technology remained available.

In this evaluation the images were viewed on a manufacturer-specific workstation (IDI). However, they could also be viewed on the main departmental GE PACS workstations. The ability to view different manufacturers' tomosynthesis images in any centre will also be important in future.

13. Conclusions and recommendations

Overall, the practical performance of the GE SenoClaire digital breast tomosynthesis mammography system was very positive. The GE tomosynthesis was found to be at least equivalent to standard supplementary mammographic views for the diagnosis of screen detected soft tissue breast lesions.

Once the special cart was available, the radiographers found the MTD very straightforward to attach and remove. Overall they found tomosynthesis imaging easy to use, with no significant issues reported. The equipment was found to be very reliable during the period of the evaluation.

The radiologists were generally content with the tomosynthesis images and workflow. There were a few issues regarding the use of the IDI workstation, probably due to limited experience with this equipment, as the units have other equipment for screen reading tasks. Since the end of the evaluation, several have commented that they miss the helpful input of tomosynthesis in assessment.

Mean glandular doses for both 2D and tomosynthesis imaging were found to be well below the national DRL, and compare favourably with other manufacturers' equipment.

The GE SenoClaire digital breast tomosynthesis system was found to be suitable for use in assessment in the NHSBSP.

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Appendix 1: Physics survey reports

A1.1 Derby, tomosynthesis commissioning, January 2014

Region	East Midlands
NHSBSP programme	Southern Derbyshire
Screening Centre	Derby
Make of x-ray unit	GE
Model	Essential
Year installed	Tomo Upgrade 2014
Serial number (manf date) - generator:	555209BU6
Serial number (manf date) - tube:	109647TX8
Serial number (manf date) - detector:	model: 5144831(march 2013) s/n 627540BU8
Software Version	ADS_56.10
Fixed / mobile	Fixed
Location	Royal Derby Hospital
Tested by	D. Whitwam & L. Toru
Date	**28th and 29th Jan 2014**
Reason for testing	**Tomo Upgrade**
Physics ID for this system	DBSE

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**Commissioning**
Comment	Commissioning tests have been performed on the tomosynthesis function of the GE Essential. Tests have followed the draft NHSBSP document 'Physics QC protocol for breast tomosynthesis'. The results from this testing will form baselines against which the results from future tests will be compared.
Reference	NHSBSP Draft document - 'Physics QC protocol for breast tomosynthesis'
Action required	None - information only
Deadline	
C2	**Patient Dose survey**
Comment	A patient dose audit should be performed to determine the patient dose form this new imaging technique. Please discuss the requirements with Medical Physics prior to data collection.
Reference	NHSBSP0604 v3 3.6.2
Action required	Audit clinical breast tomosynthesis doses following discussion with Medical Physics.
Deadline	When sufficient data is available.
C3	**Artefacts**
Comment	Artefacts were seen on the 2 cm CNR image (at aluminuim boundry). Also artefacts on MoMo uniformity at left and right edges particularly at nipple corners. See example images. These artefacts have been discussed with Bob Woodward who is investigating.
Reference	
Action required	None - information only
Deadline	

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Written by:
D. Whitwam ……

Checked by:
V Jones ……

DBSE1401 TOMO.xls Comments Medical Physics Dept, Northampton GH

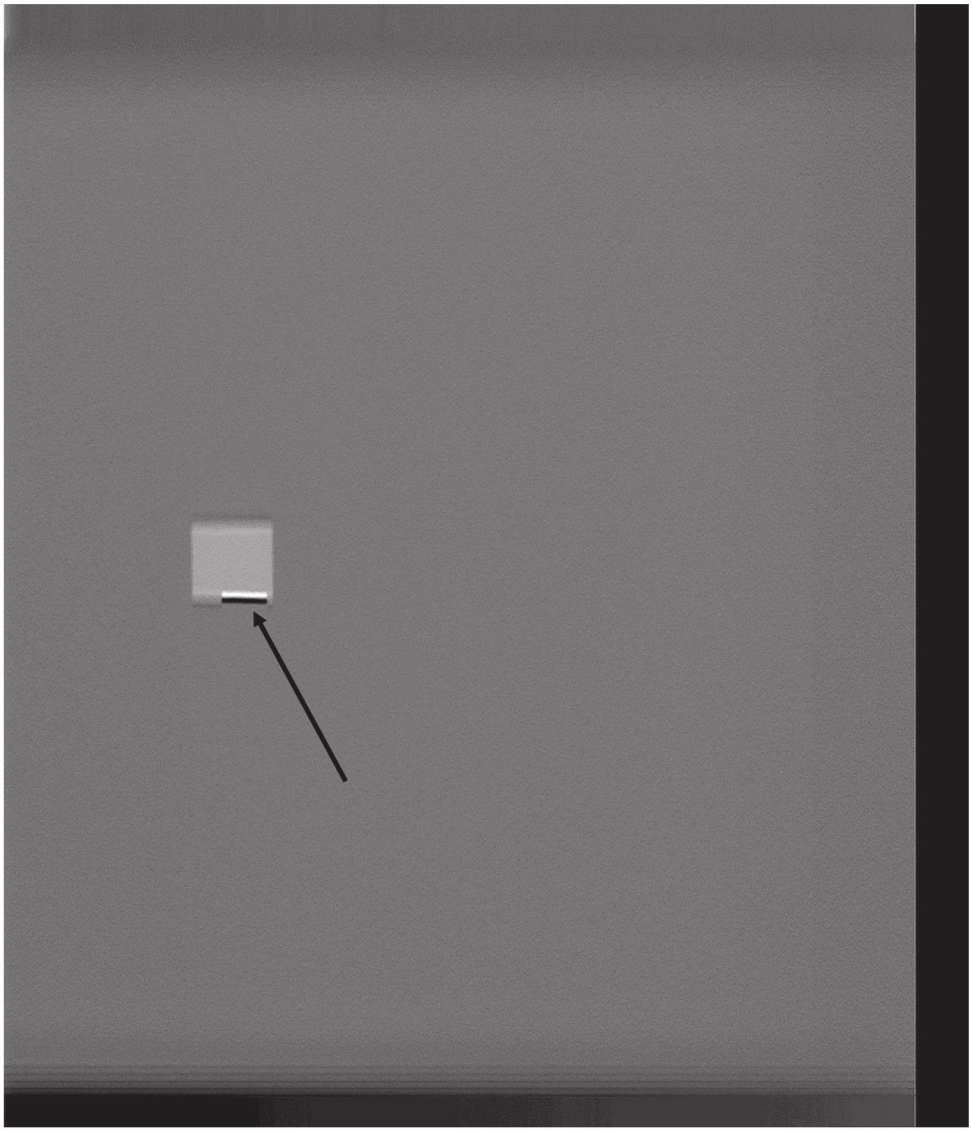
Test	Reference	Limiting values	Result	Acceptable?	Comments
Alignment					
Alignment of reconstructed image volume to target volume	NHSBSP Tomo Protocol (Draft)	**Remedial:** All markers at the top and bottom of the target volume should be brought into focus within the range of the reconstructed volume.		Acceptable	
Detector Performance					
Artefacts	NHSBSP Tomo Protocol (Draft)	See manufacturer's spec	Artefacts?		-
Detector resolution: Limiting spatial resolution	NHSBSP Tomo Protocol (Draft)	Limiting spatial resolution <75% of commissioning value	3.15 lp/mm Baseline: - lp/mm	Baseline	-
Geometric Distortion and Artefact Spread	NHSBSP Tomo Protocol (Draft)	Height of best focus	Nominal Height: 12.5 / 32.5 / 52.5	Baseline	-
			Average Slice: 28.8 / 68.15 / 109.2		
			Max deviation from average: 0.8 / 0.85 / 0.9		
		Positional accuracy	Max X Difference from mean (mm): 0.7 / 0.7 / 0.7		
			Max Y difference from mean (mm): 0.6 / 0.5 / 0.4		
		Artefact Spread	X Artefact Spread: 0.5 / 0.5 / 0.5		
			Y Artefact Spread: 0.3 / 0.3 / 0.3		
			Z resolution: 6.2 / 6.08 / 5.84		
AEC					
AEC repeatability	NHSBSP Tomo Protocol (Draft)	**Remedial**: Max dev in mAs from mean: >5% **Suspension**: Max dev in mAs from mean: >10%	Max deviation = 1%	Acceptable	-
AEC performance - Automatic mode	NHSBSP Tomo Protocol (Draft)	CNR: ±10% baseline	Auto 3D Slices	Baseline	-
			Perspex thickness / TFkV, mAs / CNR / %baseline		
			2 / MoMo26, 39 / 7.1 / -		
			3 / RhRh29, 33 / 4.6 / -		
			4 / RhRh29, 51 / 4.1 / -		
			4.5 / RhRh29, 57 / 3.9 / -		
			5 / RhRh29, 75 / 3.8 / -		
			6 / RhRh31, 81 / Missing Image / -		
			7 / RhRh31, 129 / 3.5 / -		
		CNR: ±10% baseline	Auto 3D Slabs		
			Perspex thickness / TFkV, mAs / CNR / %baseline		
			2 / MoMo26, 39 / 6.4 / -		
			3 / RhRh29, 33 / 4.2 / -		
			4 / RhRh29, 51 / 3.7 / -		
			4.5 / RhRh29, 57 / 3.5 / -		
			5 / RhRh29, 75 / 3.5 / -		
			6 / RhRh31, 81 / 3.2 / -		
			7 / RhRh31, 129 / 3.2 / -		
Exposure time		All clinical modes with standard (4.5cm) thickness	Auto 3D Slices - -	Baseline	-
		Acceptable < 2s, Achievable <1.5s	Exp time 4.5cm **9** -		
		>1s for 4cm perspex	Exp time 4cm **10** -		
		>4s for 6cm perspex	Exp time 6cm **11** -		

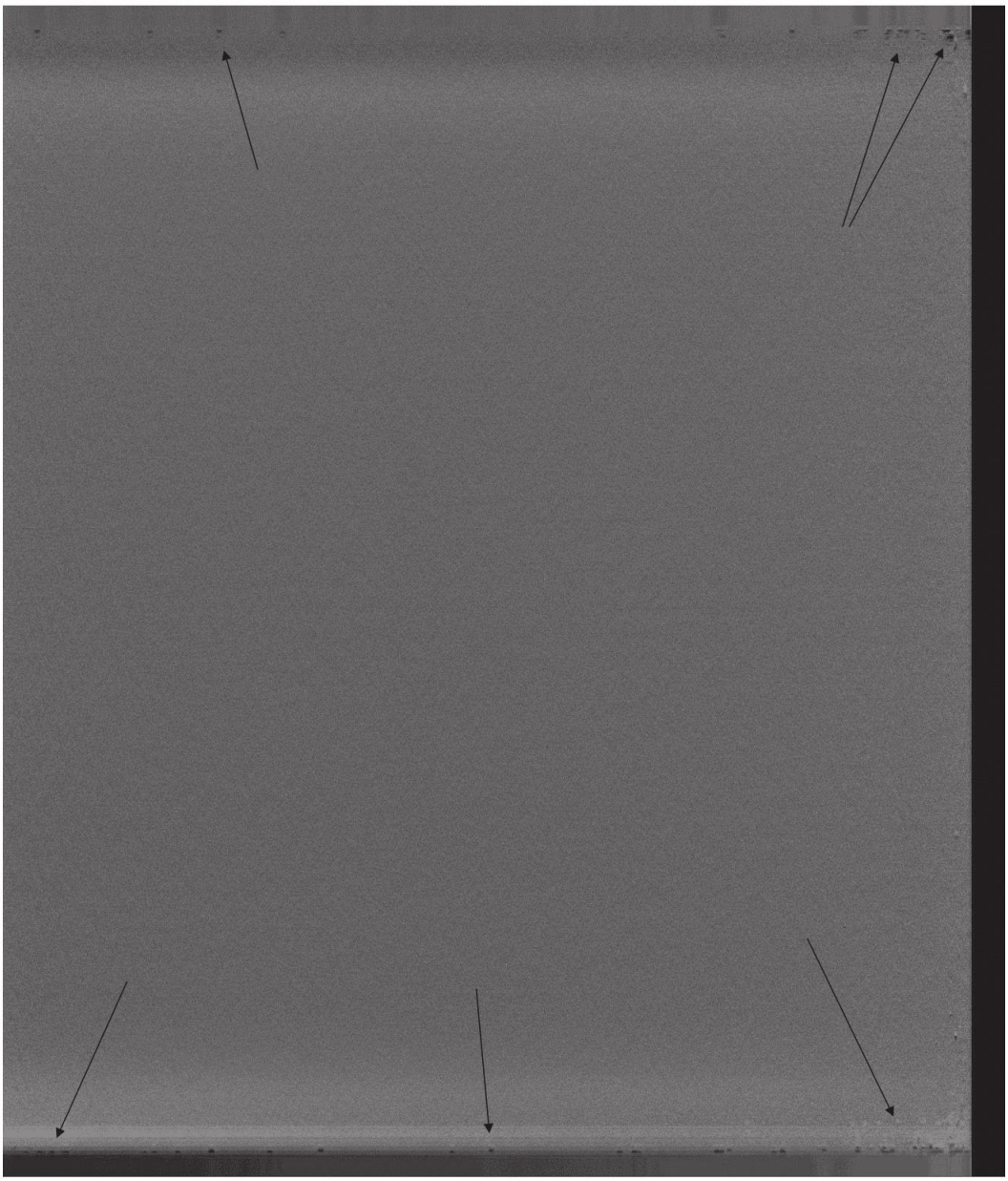
Image Quality

Test	Reference	Limiting values	Result	Acceptable?	Comments
Threshold contrast visibility - CDMAM	NHSBSP Tomo Protocol (Draft)	Threshold gold thickness Detail diameter / acceptable / achievable 2 / 0.069 / 0.038 1 / 0.091 / 0.056 0.5 / 0.15 / 0.103 0.25 / 0.352 / 0.244 0.1 / 1.68 / 1.10	Fit to predicted gold thickness RhRh29, 70mAs, 1.57mGy n/a 0.10 0.14 0.29 1.67	Baseline	-
Regular IQ tests - TORMAX	NHSBSP Tomo Protocol (Draft)	**Remedial**: No of details detected should meet NHSBSP standards for film-screen systems & be unchanged from baseline Target / Min std / Remedial / Suspension 6mm: <0.8% / <1.2% / <1.4% 0.5mm: <3% / <5% / <8% 0.25mm: <5% / <8% / <11%	MoMo28, 100mAs 0.7% 4% 8%	Acceptable	-
Regular IQ tests - TORMAM	NHSBSP Tomo Protocol (Draft)	**Remedial**: Visibility of details should be unchanged form baseline	RhRh29, 63mAs / Baseline 83 / -	Baseline	-

Dose

Test	Reference	Limiting values	Result	Acceptable?	Comments
Dose to the standard breast	NHSBSP Tomo Protocol (Draft)	Perspex thickness / Remedial (NHSBSP), Acceptable (EU2006) / Achievable (EU2006) 2 / 1.0 / <0.6 3 / 1.5 / <1.0 4 / 2.0 / <1.6 4.5 / 2.5 / <2.0 5 / 3.0 / <2.4 6 / 4.5 / <3.6 7 / 6.5 / <5.1	Auto 3D Slices / - / - **1.19** / - / - 1.07 / - / - 1.34 / - / - 1.38 / - / - 1.68 / - / - 2.10 / - / - 2.91 / - / -	Acceptable	-





Summary of Results of Automatic CDMAM reading

physics ID	DBSE
Local ID / location	0
Centre	Derby
Digital make	GE
Digital model	Essential
Date	29 January 2014
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

processed		
added px	4	cm
spacer	0	cm
mode	Auto	
kV	29	
target	Rh	
filter	Rh	
mAs	70.0	
MGD	1.57	mGy

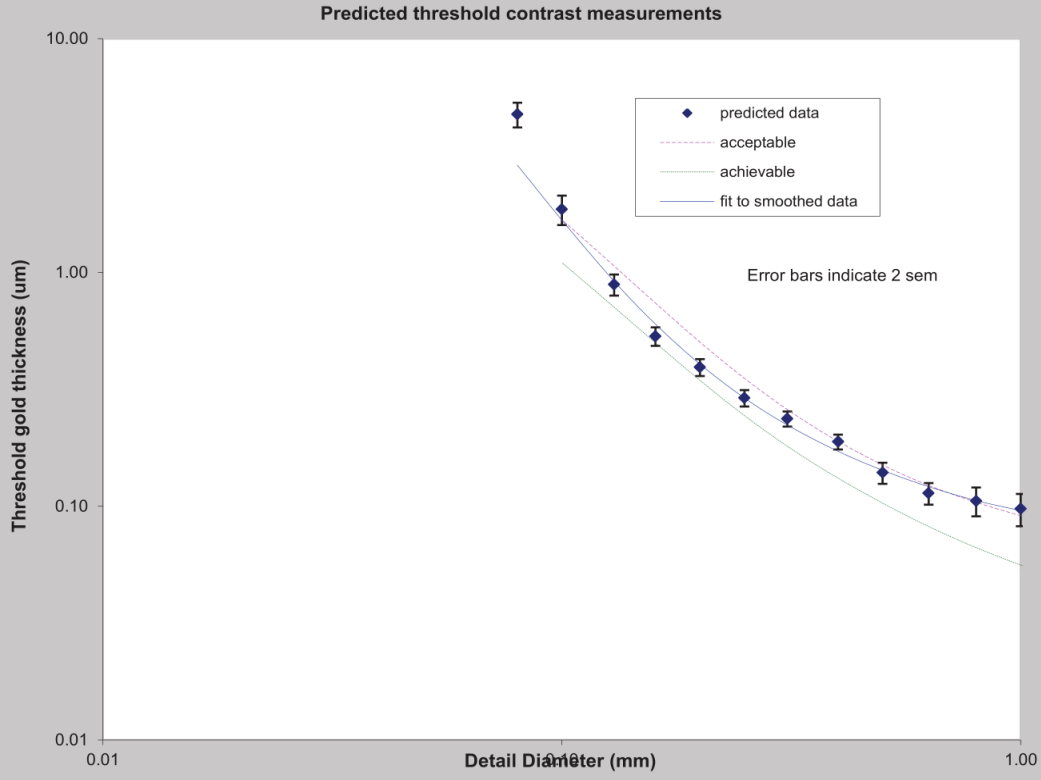
Comments: SN 1074

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.10**	**0.015**	**0.10**
0.80	0.11	0.015	0.11
0.63	0.11	0.012	0.12
0.50	**0.14**	**0.014**	**0.14**
0.40	0.19	0.014	0.17
0.31	0.24	0.018	0.22
0.25	**0.29**	**0.023**	**0.29**
0.20	0.39	0.032	0.40
0.16	0.53	0.048	0.60
0.13	0.89	0.092	0.92
0.10	**1.86**	**0.268**	**1.67**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.10**	**0.10**	**0.015**
0.5	0.15	0.103	**0.14**	**0.14**	**0.014**
0.25	0.352	0.244	**0.29**	**0.29**	**0.023**
0.1	1.68	1.1	**1.86**	**1.67**	**0.268**



A1.2 Derby, six-monthly 2D routine testing, July 2014

Region	East Midlands
NHSBSP programme	Southern Derbyshire
Screening Centre	Derby
Make of x-ray unit	GE
Model	Essential
Serial number (manf date) - generator:	555209BU6
Serial number (manf date) - tube:	109647TX8
Serial number (manf date) - detector:	model: 5144831(march 2013) s/n 627540BU8
Software Version	ADS_56.10
Fixed / mobile	Fixed
Location	Royal Derby Hospital
Tested by	D. Whitwam & L. Scallan
Date	**21 July 2014**
Reason for testing	**Routine**
Physics ID for this system	DBSE

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**Artefact**
Comment	There was a light strip (1 to 2mm) down the right hand edge of the image on images acquired with the rhodium target on 24x30 field. See example uniformity image.
Reference	
Action required	Ask engineer to investigate at next service.
Deadline	Next service

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2009
EU2006
European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition, 2006
IPEM89
The commissioning and routine testing of mammographic x-ray systems, 2005 IPEM Report No89

Written by:
D. Whitwam …….…… ……..

Checked by:
V Jones …….…… ……..

Detector Performance

Test	Reference	Limiting values	Result	Acceptable?	Comments
Uniformity - DR	NHSBSP0604v3 3.2.3	24x30 Maximum deviation from centre mean > 10%	CW-L / CW-R / Back-L / Back-R MoMo28: 3% / -1% / 7% / 3% MoRh28: 3% / -1% / 7% / 3% RhRh28: 4% / 0% / 5% / 2%	Acceptable	-
Artefacts and dead pixel dropout	NHSBSP0604v3 3.2.4	See manufacturer's spec	Artefacts?		Strip artefact down right hand edge of 24x30 Rh images.
Detector response - DR	NHSBSP0604v3 3.2.5	Detector reference air kerma >20% change from commissioning value Noise standard deviation at any measured level >10% increase from baseline SNR change >10%	RhRh29: Measured 102.6 / Baseline 101.8 / %change 1% Maximum deviation over measured range = 9% 116 / 116 / 1%	- Acceptable Acceptable Acceptable	-
Detector resolution: Square wave contrast transfer factor	NHSBSP0604v3 3.2.6.1	**Remedial**: Measured SWCTF(f) > 10% change from commissioning	MoMo26, 14mAs Bars parallel to a-c axis Measured / %baseline SWCTF(1): 0.391 / -1% SWCTF(4): 0.144 / -4%	Acceptable	-
Spatial discontinuity and resolution homogeneity	NHSBSP0604v3 3.2.7	Any evidence of discontinuities	No evidence of discontinuities	Acceptable	-
Image retention	NHSBSP0604v3 3.2.8	Image retention factor > 0.3	Image retention factor = 0.07	Acceptable	-

Detector Performance

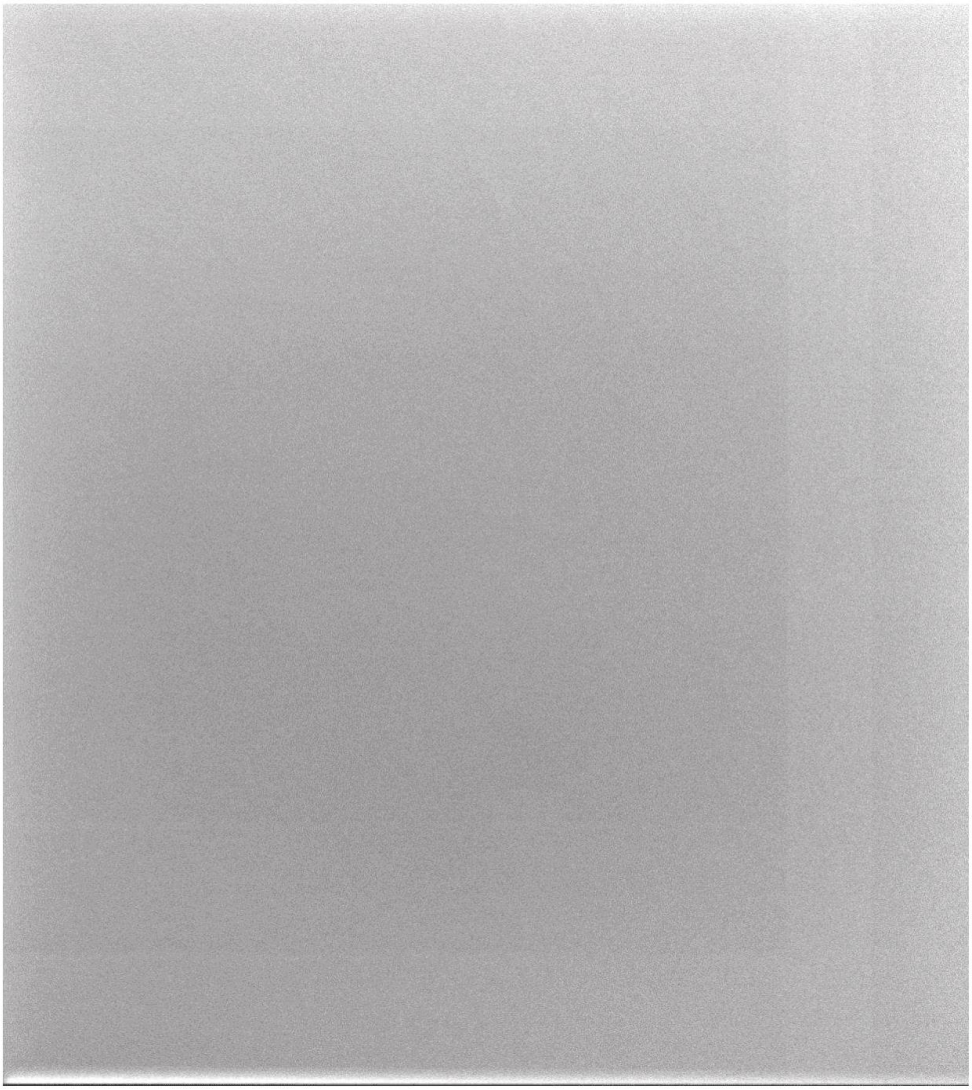
Test	Reference	Limiting values	Result	Acceptable?	Comments
Uniformity - DR	NHSBSP0604v3 3.2.3	24x30 Maximum deviation from centre mean > 10%	CW-L / CW-R / Back-L / Back-R MoMo28: 3% / -1% / 7% / 3% MoRh28: 3% / -1% / 7% / 3% RhRh28: 4% / 0% / 5% / 2%	Acceptable	-
Artefacts and dead pixel dropout	NHSBSP0604v3 3.2.4	See manufacturer's spec	Artefacts?		Strip artefact down right hand edge of 24x30 Rh images.
Detector response - DR	NHSBSP0604v3 3.2.5	Detector reference air kerma >20% change from commissioning value Noise standard deviation at any measured level >10% increase from baseline SNR change >10%	RhRh29 — Measured / Baseline / %change 102.6 / 101.8 / 1% Maximum deviation over measured range = 9% 116 / 116 / 1%	- Acceptable Acceptable Acceptable	-
Detector resolution: Square wave contrast transfer factor	NHSBSP0604v3 3.2.6.1	**Remedial**: Measured SWCTF(f) > 10% change from commissioning	MoMo26, 14mAs — Bars parallel to a-c axis Measured / %baseline SWCTF(1): 0.391 / -1% SWCTF(4): 0.144 / -4%	Acceptable	-
Spatial discontinuity and resolution homogeneity	NHSBSP0604v3 3.2.7	Any evidence of discontinuities	No evidence of discontinuities	Acceptable	-
Image retention	NHSBSP0604v3 3.2.8	Image retention factor > 0.3	Image retention factor = 0.07	Acceptable	-

Image Quality

Test	Reference	Limiting values	Result	Acceptable?	Comments
Threshold contrast visibility - CDMAM	NHSBSP0604v3 3.5.1	Detail diameter / Threshold gold thickness: acceptable / achievable 2: 0.069 / 0.038 1: 0.091 / 0.056 0.5: 0.15 / 0.103 0.25: 0.352 / 0.244 0.1: 1.68 / 1.10	Fit to predicted gold thickness RhRh29, 63mAs, 1.38mGy n/a 0.08 0.12 0.26 0.99	Acceptable	-
Regular IQ tests - TORMAX	NHSBSP0604v3 3.5.1	**Remedial**: No of details detected should meet NHSBSP standards for film-screen systems & be unchanged from baseline Target / Min std / Remedial / Suspension 6mm: <0.8% / <1.2% / <1.4% 0.5mm: <3% / <5% / <8% 0.25mm: <5% / <8% / <11%	MoMo28, 100mAs 0.4% 3% 6%	Acceptable	-
Regular IQ tests - TORMAM	NHSBSP0604v3 3.5.1	**Remedial**: Visibility of details should be unchanged form baseline	RhRh29, 67mAs: 99 Baseline: 100	Acceptable	-

Dose

Test	Reference	Limiting values	Result	Acceptable?	Comments
Dose to the standard breast	NHSBSP0604v3 3.6.1 EU2006 2.5.1	Perspex thickness / Remedial (NHSBSP), Acceptable (EU2006) / Achievable (EU2006) 2: 1.0 / <0.6 3: 1.5 / <1.0 4: 2.0 / <1.6 4.5: 2.5 / <2.0 5: 3.0 / <2.4 6: 4.5 / <3.6 7: 6.5 / <5.1	STD / Dose **1.10** / 0.56 - 0.95 / 0.78 - 1.34 / 0.98 - 1.39 / 1.06 - 1.67 / 1.27 - 1.62 / 1.32 - 1.61 / 1.60 -	Acceptable	-



A1.3 Derby, 6-monthly tomosynthesis routine testing, July 2014

Region	East Midlands
NHSBSP programme	Southern Derbyshire
Screening Centre	Derby
Make of x-ray unit	GE
Model	Essential
Year installed	Tomo Upgrade 2014
Serial number (manf date) - generator:	555209BU6
Serial number (manf date) - tube:	109647TX8
Serial number (manf date) - detector:	model: 5144831(march 2013) s/n 627540BU8
Software Version	ADS_56.10
Fixed / mobile	Fixed
Location	Royal Derby Hospital
Tested by	D. Whitwam & L. Scallan
Date	**28 July 2014**
Reason for testing	**Routine 3D Tomosynthesis Tests**
Physics ID for this system	DBSE

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**None**
Comment	
Reference	
Action required	
Deadline	

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2009
EU2006
European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition, 2006
IPEM89
The commissioning and routine testing of mammographic x-ray systems, 2005 IPEM Report No89

Written by:
D. Whitwam…….…… ……..

Checked by:
V Jones ……..…… ……..

Alignment

Test	Reference	Limiting values	Result					Acceptable?	Comments
Alignment of x-ray field to the light field	Draft NHSBSP TOMO protocol	**Remedial:** Misalignment >5mm along any edge		CWE	Nipple edge	Left	Right	Acceptable	-
			TF,24x30,-,Mo	-2	0	2	4		
			TF,24x30,-,Rh	-3	0	2	4		
			TF,18x24,-,Mo	3	0	2	6		
			TF,18x24,-,Rh	3	0	2	5		
Alignment of x-ray field to imaged field / detector	Draft NHSBSP TOMO protocol	**Remedial:** >5mm or <0mm overlap of image by x-ray field on all sides **Suspension:** >10mm overlap or >2mm unexposed border along CW edge with respect to image >10mm overlap along left or right edge with respect to image		CWE	Nipple edge	Left	Right	Acceptable	-
			TF,24x30,-,Mo	2		6	4		
			TF,24x30,-,Rh	1		5	6		
			TF,18x24,-,Mo	1		0	1		
			TF,18x24,-,Rh	1		0	0		
Alignment of reconstructed image volume to target volume	Draft NHSBSP TOMO protocol	**Remedial:** All markers at the top and bottom of the target volume should be brought into focus within the range of the reconstructed volume.	Markers are in good focus in slices 3 and 61 of 65 and slabs 1 and 7 of 7						

Detector Performance

Test	Reference	Limiting values	Result				Acceptable?	Comments
Artefacts and dead pixel dropout	Draft NHSBSP TOMO protocol	See manufacturer's spec	Artefacts?	Similar artefact at aluminium boundry edge as seen previously.				-
Detector resolution: Limiting spatial resolution	Draft NHSBSP TOMO protocol	Limiting spatial resolution <75% of commissioning value	3.55 x 5 lp/mm		Baseline:	3.15 lp/mm	Acceptable	-
Geometric Distortion and Artefact Spread	Draft NHSBSP TOMO protocol							-
		Height of best focus	Nominal Height	12.5	32.5	52.5	Acceptable	
			Average Slice	12	12	11.6		
			Max deviation from average	3.6	3.6	2.0		
		Positional accuracy	Max X Difference from mean (mm)	1.0	1.0	1.0		
			Max Y difference from mean (mm)	6.2	6.0	5.8		
		Artefact Spread	X Artefact Spread	0.6	0.6	0.5		
			Y Artefact Spread	0.2	0.2	0.2		
			Z resolution	6.2	6.0	5.8		

Test	Reference	Limiting values	Result	Acceptable?	Comments
AEC					
AEC repeatability	Draft NHSBSP TOMO protocol	**Remedial**: Max dev in mAs from mean: >5% **Suspension**: Max dev in mAs from mean: >10%	Max mAs deviation = 3% mAx SNR deviation = 5%	Acceptable	-
AEC performance - Automatic mode	NHSBSP0604v3 3.3.2	CNR: ±10% baseline	Auto 3D Slices	Acceptable	-
			Perspex thickness / TFkV, mAs / CNR / %baseline 2 / MoMo26, 42 / 7.4 / 4% 3 / RhRh29, 35 / 4.6 / 1% 4 / RhRh29, 51 / 4.2 / 1% 4.5 / RhRh29, 57 / 3.8 / -2% 5 / RhRh29, 75 / 3.8 / 0% 6 / RhRh31, 85 / 3.6 / 0% 7 / RhRh31, 135 / 3.6 / 4%		
		CNR: ±10% baseline	Auto 3D Slabs	Acceptable	-
			Perspex thickness / TFkV, mAs / CNR / %baseline 2 / , / 6.6 / 3% 3 / , / 4.1 / -1% 4 / , / 3.7 / -1% 4.5 / , / 3.4 / -2% 5 / , / 3.4 / -3% 6 / , / 3.2 / 2% 7 / , / 3.3 / 4%		
Exposure time	EU2006 2.4.3	All clinical modes with standard (4.5cm) thickness Acceptable < 2s, Achievable <1.5s	Auto 3D Slices - - Exp time 4.5cm **9**	Acceptable	-
	IPEM89 5.7.3	>1s for 4cm perspex >4s for 6cm perspex	Exp time 4cm **9** Exp time 6cm **10**		

Image Quality

Threshold contrast visibility - CDMAM

Reference: NHSBSP0604v3 3.5.1

Detail diameter	Threshold gold thickness acceptable	Threshold gold thickness achievable	Fit to predicted gold thickness RhRh29, 72mAs, 1.55mGy
2	0.069	0.038	n/a
1	0.091	0.056	0.09
0.5	0.15	0.103	0.15
0.25	0.352	0.244	0.29
0.1	1.68	1.10	1.30

Acceptable? Acceptable

Comments: -

Regular IQ tests - TORMAX

Reference: NHSBSP0604v3 3.5.1

Limiting values: **Remedial**: No of details detected should meet NHSBSP standards for film-screen systems & be unchanged from baseline

	Target	Min std / Remedial	Suspension	MoMo28, 100mAs
6mm	<0.8%	<1.2%	<1.4%	0.5%
0.5mm	<3%	<5%	<8%	3%
0.25mm	<5%	<8%	<11%	6%

Acceptable? Acceptable

Comments: -

Regular IQ tests - TORMAM

Reference: NHSBSP0604v3 3.5.1

Limiting values: **Remedial**: Visibility of details should be unchanged form baseline

RhRh29, 72mAs	Baseline
86	83

Acceptable? Acceptable

Comments: -

Dose

Dose to the standard breast

Reference: NHSBSP0604v3 3.6.1, EU2006 2.5.1

Perspex thickness	Remedial (NHSBSP), Acceptable (EU2006)	Achievable (EU2006)	Auto 3D Slices	-	-
2	1.0	<0.6	**1.31**	-	-
3	1.5	<1.0	1.10	-	-
4	2.0	<1.6	1.30	-	-
4.5	2.5	<2.0	1.34	-	-
5	3.0	<2.4	1.63	-	-
6	4.5	<3.6	2.11	-	-
7	6.5	<5.1	2.92	-	-

Acceptable? Acceptable

Comments: -

Test	Reference	Limiting values	Result	Acceptable?	Comments
Compression					
Maximum	IPEM89 5.6.5	<130N, >200N	Force = at set maximum -	-	Not Tested
Thickness gauge accuracy		±5mm	Maximum error = 0 mm	-	Not Tested
Alignment					
Alignment of x-ray field to the light field	Draft NHSBSP TOMO protocol	**Remedial:** Misalignment >5mm along any edge	CWE / Nipple edge / Left / Right BF,24x30,-,Rh: -1 / 0 / -3 / 5 BF,24x30,,Mo: -1 / 0 / -2 / 7 BF,18x24,C,Mo: 2 / 0 / 5 / 7 BF,18x24,C,Rh: 3 / 0 / 5 / 5	Acceptable	Acceptable within the limitations of the measurement
Alignment of x-ray field to imaged field / detector	Draft NHSBSP TOMO protocol	**Remedial:** >5mm or <0mm overlap of image by x-ray field on all sides **Suspension:** >10mm overlap or >2mm unexposed border along CW edge with respect to image >10mm overlap along left or right edge with respect to image	CWE / Nipple edge / Left / Right BF,24x30,-,Rh: 3 / 0 / 5 BF,24x30,,Mo: 4 / 3 / 6 BF,18x24,C,Mo: 0 / 3 / 0 BF,18x24,C,Rh: 0 / 3 / 0	Acceptable	Acceptable within the limitations of the measurement
Alignment of reconstructed image volume to target volume	Draft NHSBSP TOMO protocol	**Remedial:** All markers at the top and bottom of the target volume should be brought into focus within the range of the reconstructed volume.		Acceptable	
Detector Performance					
Artefacts and dead pixel dropout	Draft NHSBSP TOMO protocol	See manufacturer's spec	Artefacts? An artefact appeared on the TORMAX image and appeared on all slices. The cause of the artecfact is unknown.		It is recognised that the limited data set acquired for tomosynthesis will result in image artefacts particularly at the lateral edges of the volume. The overall appearance of the images however was uniform and without significant unexpected artefacts.
Detector resolution: Limiting spatial resolution	Draft NHSBSP TOMO protocol	Limiting spatial resolution <75% of commissioning value	3.55 lp/mm Baseline: lp/mm	Baseline	-
Geometric Distortion and Artefact Spread	Draft NHSBSP TOMO protocol	Height of best focus Positional accuracy Artefact Spread	Nominal Height: 12.5 / 32.5 / 52.5 Average Slice: 28.7 / 69.8 / 109.9 Max deviation from average: 0.7 / 0.8 / 1.1 Max X Difference from mean (mm): 0.4 / 0.5 / 0.2 Max Y difference from mean (mm): 0.5 / 0.4 / 0.5 X Artefact Spread: 0.5 / 0.4 / 0.4 Y Artefact Spread: 0.3 / 0.3 / 0.2 Z resolution: 12.48 / 12.06 / 11.75	Baseline	-

Summary of Results of Automatic CDMAM reading

physics ID	DBSE	unprocessed		
Local ID / location	Room 1	added px	4	cm
Centre	Derby	spacer	0	cm
Digital make	GE	mode	Auto	
Digital model	Essential SenoClaire	kV	29	
Date	28 July 2014	target	Rh	
manufacturer of X-ray set	GE	filter	Rh	
model of X-ray set		mAs	71.6	
model of CR plate		MGD	1.55	mGy

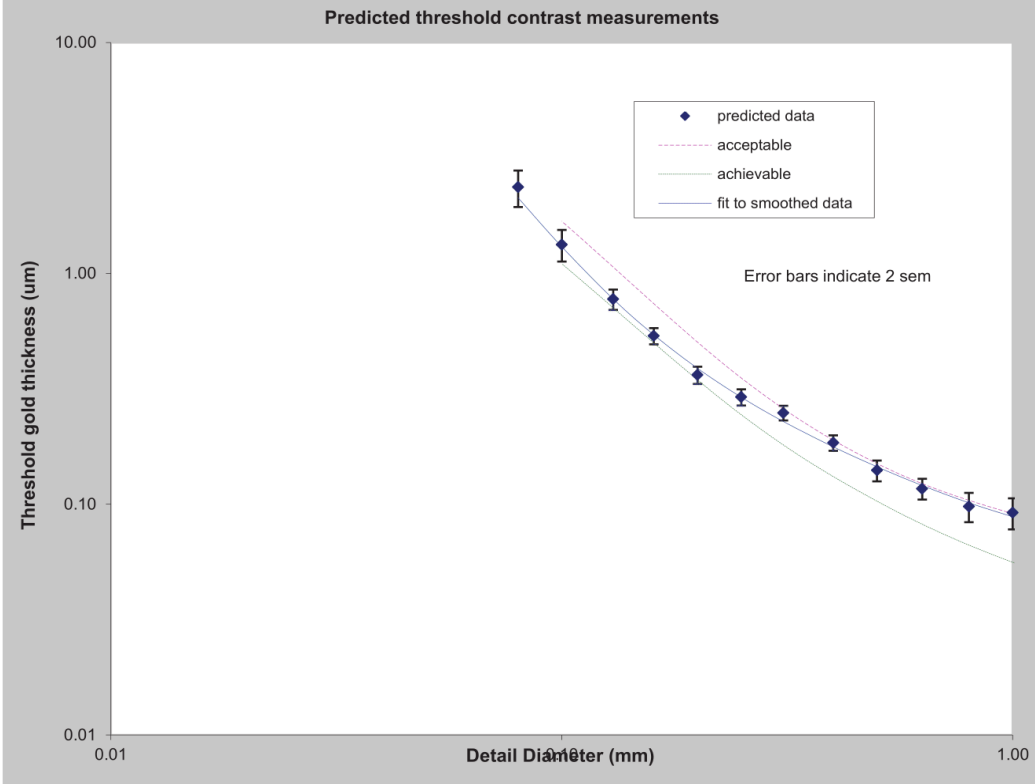
Comments: SN 1074

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.09**	**0.014**	**0.09**
0.80	0.10	0.014	0.10
0.63	0.12	0.012	0.12
0.50	**0.14**	**0.015**	**0.15**
0.40	0.18	0.014	0.18
0.31	0.25	0.018	0.23
0.25	**0.29**	**0.023**	**0.29**
0.20	0.36	0.031	0.39
0.16	0.54	0.043	0.54
0.13	0.77	0.077	0.77
0.10	**1.33**	**0.209**	**1.30**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.09**	**0.09**	**0.014**
0.5	0.15	0.103	**0.14**	**0.15**	**0.015**
0.25	0.352	0.244	**0.29**	**0.29**	**0.023**
0.1	1.68	1.1	**1.33**	**1.30**	**0.209**



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A.1.4 Nottingham, tomosynthesis commissioning, October 2013

Region	East Midlands
NHSBSP programme	Notts
Screening Centre	Nottingham
Make of x-ray unit	GE
Model	Essential
Year installed	MTD installed 2013
Software Version	ADS 56.10 Reconstruction Package VERSION RECON_01.10.1
Fixed / mobile	Fixed
Location	Room 2
Tested by	V. Jones & D. Whitwam
Date	**02 October 2013**
Reason for testing	**Commissioning Tomosynthesis**
Physics ID for this system	NGDT

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**Commissioning**
Comment	Commissioning tests have been performed on the tomosynthesis attachment (Motorised Tomosynthesis Device - MTD) of the GE Essential in room 1. Tests have followed the draft NHSBSP document 'Routine quality control tests for breat tomosynthesis'. Due to the limited experience of tomosynthesis QA testing nationally, remedial levels are yet to be agreed on. The results from this testing will therefore form baselines against which the results from future tests will be compared. No tests have been performed on the system in its 2D configuration using the MTD . It is therefore recomended that 2D images continue to be acquired with the standard grid/Bucky cover rather than with the MTD.
Reference	NHSBSP Draft document - 'Routine quality control tests for breat tomosynthesis'
Action required	Do not use the MTD to acquire 2D images until this aspect has been tested by medical physics.
Deadline	
C2	**Patient Dose survey**
Comment	A patient dose audit should be performed to determine the patient dose form this new imaging technique. Please discuss the requirments with Medical Physics prior to data collection.
Reference	NHSBSP0604 v3 3.6.2
Action required	Audit clinical breast tomosynthesis doses following discussion with Medical Physics.
Deadline	When sufficient data is available.
C3	**Compression**
Comment	Compression force and thickness were not tested at the time of the survey. Compression thickness can be approximated from the CNR test and appears oto be satisfactory. Compression force should be tested prior to clinical use.
Reference	
Action required	Medical Physics to test compression force prior to clinical use.
Deadline	Prior to clinical use

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2009
EU2006
European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition, 2006
IPEM89
The commissioning and routine testing of mammographic x-ray systems, 2005 IPEM Report No89

Written by:
D. Whitwam…… ……

Checked by:
V Jones …… ……

Test	Reference	Limiting values	Result				Acceptable?	Comments
Compression								
Maximum	IPEM89 5.6.5	<130N, >200N	Force =		at set maximum -		-	Not Tested
Thickness gauge accuracy		±5mm	Maximum error =	0	mm		-	Not Tested
Alignment								
Alignment of x-ray field to the light field	Draft NHSBSP TOMO protocol	**Remedial:** Misalignment >5mm along any edge		CWE	Nipple edge	Left	Right	Acceptable	Acceptable within the limitations of the measurement
			BF,24x30,-,Rh	-1	0	-3	5		
			BF,24x30,,Mo	-1	0	-2	7		
			BF,18x24,C,Mo	2	0	5	7		
			BF,18x24,C,Rh	3	0	5	5		
Alignment of x-ray field to imaged field / detector	Draft NHSBSP TOMO protocol	**Remedial:** >5mm or <0mm overlap of image by x-ray field on all sides **Suspension:** >10mm overlap or >2mm unexposed border along CW edge with respect to image >10mm overlap along left or right edge with respect to image		CWE	Nipple edge	Left	Right	Acceptable	Acceptable within the limitations of the measurement
			BF,24x30,-,Rh	3		0	5		
			BF,24x30,,Mo	4		3	6		
			BF,18x24,C,Mo	0		3	0		
			BF,18x24,C,Rh	0		3	0		
Alignment of reconstructed image volume to target volume	Draft NHSBSP TOMO protocol	**Remedial:** All markers at the top and bottom of the target volume should be brought into focus within the range of the reconstructed volume.						Acceptable	
Detector Performance								
Artefacts and dead pixel dropout	Draft NHSBSP TOMO protocol	See manufacturer's spec	Artefacts?	An artefact appeared on the TORMAX image and appeared on all slices. The cause of the artecfact is unknown.					It is recognised that the limited data set acquired for tomosynthesis will result in image artefacts particularly at the lateral edges of the volume. The overall appearance of the images however was uniform and without significant unexpected artefacts.
Detector resolution: Limiting spatial resolution	Draft NHSBSP TOMO protocol	Limiting spatial resolution <75% of commissioning value	3.55 lp/mm		Baseline:		lp/mm	Baseline	-
Geometric Distortion and Artefact Spread	Draft NHSBSP TOMO protocol	Height of best focus	Nominal Height		12.5	32.5	52.5	Baseline	-
			Average Slice		28.7	69.8	109.9		
			Max deviation from average		0.7	0.8	1.1		
		Positional accuracy	Max X Difference from mean (mm)		0.4	0.5	0.2		
			Max Y difference from mean (mm)		0.5	0.4	0.5		
		Artefact Spread	X Artefact Spread		0.5	0.4	0.4		
			Y Artefact Spread		0.3	0.3	0.2		
			Z resolution		12.48	12.06	11.75		

Test	Reference	Limiting values	Result	Acceptable?	Comments
AEC					
AEC repeatability Taken from CDMAM results	Draft NHSBSP TOMO protocol	**Remedial**: Max dev in mAs from mean: >5% **Suspension**: Max dev in mAs from mean: >10%	Max deviation = 3%	Acceptable	-
		CNR: ±10% baseline	no fine view or premium (Slices)		
			Perspex thickness: 2 — TFkV, mAs: MoMo26, 44 — CNR: 7.3 — %baseline: -		
			Perspex thickness: 4.5 — TFkV, mAs: RhRh29, 63 — CNR: 3.8 — %baseline: -		
			Perspex thickness: 7 — TFkV, mAs: RhRh31, 143 — CNR: 3.6 — %baseline: -		
		CNR: ±10% baseline	no fine view or premium (Slabs)		
			Perspex thickness: 2 — TFkV, mAs: MoMo26, 44 — CNR: 6.9 — %baseline: -		
			Perspex thickness: 4.5 — TFkV, mAs: RhRh29, 63 — CNR: 3.5 — %baseline: -		
			Perspex thickness: 7 — TFkV, mAs: RhRh31, 143 — CNR: 3.3 — %baseline: -		
Image Quality					
Threshold contrast visibility - CDMAM	Draft NHSBSP TOMO protocol	Detail diameter: 2 — Threshold gold thickness acceptable: 0.069 — achievable: 0.038	Fit to predicted gold thickness RhRh29, 76mAs, 1.5mGy: n/a	Acceptable	-
		1 — 0.091 — 0.056	0.09		
		0.5 — 0.15 — 0.103	0.14		
		0.25 — 0.352 — 0.244	0.31		
		0.1 — 1.68 — 1.10	1.65		
Regular IQ tests - TORMAX	Draft NHSBSP TOMO protocol	**Remedial**: No of details detected should be unchanged from baseline (2D limits provided for comparison) 6mm — Target: <0.8% — Min std / Remedial: <1.2% — Suspension: <1.4%	RhRh31, 90mAs: 0.4%	Acceptable	-
		0.5mm — <3% — <5% — <8%	3%		
		0.25mm — <5% — <8% — <11%	6%		
Regular IQ tests - TORMAM	Draft NHSBSP TOMO protocol	**Remedial**: Visibility of details should be unchanged form baseline	RhRh29, 72mAs: 87 — Baseline: -	Baseline	-
Dose					
Dose to the standard breast	Draft NHSBSP TOMO protocol	Perspex thickness: 2 — Remedial (NHSBSP), Acceptable (EU2006): 1.0 — Achievable (EU2006): <0.6	no fine view or premium (Slices): **1.17** - -	Baseline	The MGD calculated using the UK method exceeds the NHSBSP0604 remedial level at 2cm perspex. This remedial levels however, were derived for 2D mammography and may not be valid for tomosynthesis as the additional information generated by tomosynthesis may justify the small additional dose delivered. The Displayed MGD (claculated using a non UK method) gives a result equal to the remedial level at 2cm perspex. MGD at all other perspex thicknesses are small compared with the 2D remedial level.
		4.5 — 2.5 — <2.0	1.33 - -		
		7 — 6.5 — <5.1	2.80 - -		

Summary of Results of Automatic CDMAM reading

physics ID	NGDT TOMO
Local ID / location	0
Centre	Nottingham
Digital make	GE
Digital model	Essential TOMO
Date	02 October 2013
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

TOMO		
added px	4	cm
spacer	0	cm
mode	AUTO	
kV	29	
target	Rh	
filter	Rh	
mAs	75.5	
MGD	1.48	mGy

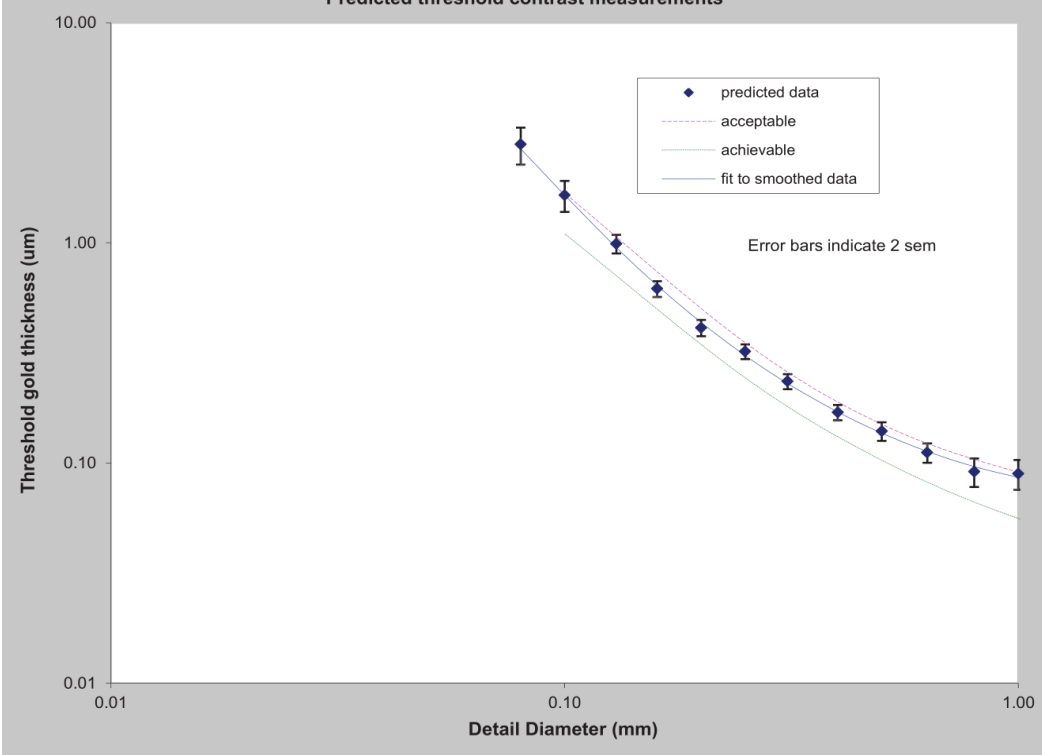
Comments: SN 1074

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.09**	**0.014**	**0.09**
0.80	0.09	0.013	0.10
0.63	0.11	0.011	0.11
0.50	**0.14**	**0.014**	**0.14**
0.40	0.17	0.014	0.17
0.31	0.23	0.018	0.23
0.25	**0.32**	**0.025**	**0.31**
0.20	0.41	0.035	0.43
0.16	0.62	0.051	0.64
0.13	0.99	0.095	0.95
0.10	**1.64**	**0.264**	**1.65**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.09**	**0.09**	**0.014**
0.5	0.15	0.103	**0.14**	**0.14**	**0.014**
0.25	0.352	0.244	**0.32**	**0.31**	**0.025**
0.1	1.68	1.1	**1.64**	**1.65**	**0.264**



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A1.5 Nottingham, 6-monthly 2D routine testing, March 2014

Region	East Midlands
NHSBSP programme	Notts
Screening Centre	Nottingham
Make of x-ray unit	GE
Model	Essential
Year installed	2013
System ID:	00611MAS18
Serial number (manf date) - generator:	628319BU6
Serial number (manf date) - tube:	133955TX5
Serial number (manf date) - detector:	628660BU3
Software Version	56.10
Fixed / mobile	Fixed
Location	Room 1, NBI
Tested by	D. Whitwam & L. Toru
Date	**11 March 2014**
Reason for testing	**Routine Standard 2D**
Physics ID for this system	NGDT
Local ID	Room 1

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**None**
Comment	
Reference	
Action required	
Deadline	

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2009
EU2006
European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition, 2006
IPEM89
The commissioning and routine testing of mammographic x-ray systems, 2005 IPEM Report No89

Written by:
David Whitwam……..……..……..

Checked by:
V Jones ……..…… ……..

Test	Reference	Limiting values	Result					Acceptable?	Comments
kV calibration									
Max kV error in useful clinical range (25-32 kV)	IPEM89 5.6.7				Broad	Fine			
		Remedial: ±1kV	Maximum error:		0.1	-		Acceptable	-
kV with set kV=28		Suspension: ±2kV	kV at 28 set:		28.0	-			
HVL and filtration									
MoMo, 30kV, CP out		<0.3 or >0.4 mmAl (for MoMo, 30kV)			0.35			Acceptable	-
Tube output									
Output repeatability - MoMo - compression plate in	IPEM89 5.6.9	>±5% mean			0.2%			Acceptable	-
µGy/mAs @ 50cm (MoMo)		>120µGy/mAs @50cm			192			Acceptable	
Variation of output with tube voltage - MoMo		The relationship between kV and output should be near linear	OP@28kV		47.9	µGy/mAs at 1m		Acceptable	
Variation of output with tube voltage - MoRh			OP@28kV		38.0	µGy/mAs at 1m		Acceptable	
Variation of output with tube voltage - RhRh			OP@28kV		35.2	µGy/mAs at 1m		Acceptable	
Variation with mAs - broad focus		±10%			4.3%			Acceptable	
Safety checks									
Mechanical and safety function	IPEM89 5.3							Acceptable	-
Compression									
Maximum	IPEM89 5.6.5	<130N, >200N		Force =	200	at set maximum -19		Acceptable	-
Thickness gauge accuracy		±5mm		Maximum error =	2	mm		Acceptable	-
Focal spot									
Broad focus	IPEM89 5.6.6				Length	Width			
			Mo	Broad	0.40	0.47		Acceptable	-
			Rh	Broad	0.37	0.40			
Alignment									
Alignment of x-ray field to the light field	NHSBSP0604v3 3.1.1	**Remedial:** Misalignment >5mm along any edge		CWE	Nipple edge	Left	Right	Acceptable	-
			BF,24x30,-,Mo	0	-4	0	4		
			BF,24x30,-,Rh	0	-4	-1	3		
			BF,18x24,C,Mo	1	-1	-1	2		
			BF,18x24,C,Rh	0	-1	-1	2		
			BF,18x24,L,Mo	0	-2	-2	3		
			BF,18x24,L,Rh	0	-3	-2	3		
			BF,18x24,R,Mo	0	-3	-2	3		
			BF,18x24,R,Rh	0	-3	-2	2		
Alignment of x-ray field to imaged field / detector	NHSBSP0604v3 3.1.1	**Remedial:** >5mm or <0mm overlap of image by x-ray field on all sides **Suspension:** >10mm overlap or >2mm unexposed border along CW edge with respect to image >10mm overlap along left or right edge with respect to image		CWE	Nipple edge	Left	Right	Acceptable	-
			BF,24x30,-,Mo	2	3	2	4		
			BF,24x30,-,Rh	1	4	3	4		
			BF,18x24,C,Mo	2	4	3	4		
			BF,18x24,C,Rh	1	4	2	3		
			BF,18x24,L,Mo	2	4	2	4		
			BF,18x24,L,Rh	2	4	2	3		
			BF,18x24,R,Mo	2	4	2	3		
			BF,18x24,R,Rh	1	4	2	2		

AEC

Test	Reference	Limiting values		Result				Acceptable?	Comments
AEC repeatability	NHSBSP0604v3 3.3.1	**Remedial**: Max dev in mAs from mean: >5% **Suspension**: Max dev in mAs from mean: >10%		Max deviation =	0%			Acceptable	-
AEC performance - Automatic mode	NHSBSP0604v3 3.3.2	CNR: ±10% baseline	STD	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo26, 34	33.4	3%		
				3	MoRh27, 41	23.9	-2%		
				4	RhRh29, 49	20.1	2%		
				4.5	RhRh29, 55	18.6	8%		
				5	RhRh29, 73	17.3	2%		
				6	RhRh31, 92	15.8	5%		
				7	RhRh31, 140	14.8	3%		
		CNR: ±10% baseline	CONT	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo26, 41	36.7	6%		
				3	MoRh27, 60	30.3	-2%		
				4	RhRh29, 66	23.7	5%		-
				4.5	RhRh29, 70	20.6	6%	Acceptable	
				5	RhRh29, 92	19.6	3%		
				6	RhRh30, 123	18.5	7%		
				7	RhRh30, 182	16.3	5%		
		CNR: ±10% baseline	DOSE	Perspex thickness	TFkV, mAs	CNR	%baseline		
				2	MoMo27, 19	26.1	9%		
				3	MoRh27, 32	21.4	1%		
				4	RhRh29, 40	18.0	3%		
				4.5	RhRh29, 46	16.6	6%		
				5	RhRh29, 61	16.5	9%		
				6	RhRh30, 83	14.6	3%		
				7	RhRh30, 127	13.0	1%		
Exposure time	EU2006 2.4.3	All clinical modes with standard (4.5cm) thickness			STD	CONT	DOSE		
		Acceptable < 2s, Achievable <1.5s		Exp time 4.5cm	0.90	1.15	0.74	Acceptable	-
	IPEM89 5.7.3	>1s for 4cm perspex		Exp time 4cm	0.80	**1.08**	0.65		
		>4s for 6cm perspex		Exp time 6cm	1.53	2.02	1.34		

Image Quality

Test	Reference	Limiting values	Result	Acceptable?	Comments
Threshold contrast visibility - CDMAM	NHSBSP0604v3 3.5.1	Detail diameter / Threshold gold thickness: acceptable / achievable 2: 0.069 / 0.038 1: 0.091 / 0.056 0.5: 0.15 / 0.103 0.25: 0.352 / 0.244 0.1: 1.68 / 1.10	Fit to predicted gold thickness RhRh29, 73mAs, 1.41mGy n/a 0.07 0.12 0.25 0.94	Acceptable	-
Regular IQ tests - TORMAX	NHSBSP0604v3 3.5.1	**Remedial**: No of details detected should meet NHSBSP standards for film-screen systems & be unchanged from baseline Target / Min std / Remedial / Suspension 6mm: <0.8% / <1.2% / <1.4% 0.5mm: <3% / <5% / <8% 0.25mm: <5% / <8% / <11%	MoMo28, 100mAs 0.5% 3% 5%	Acceptable	-
Regular IQ tests - TORMAM	NHSBSP0604v3 3.5.1	**Remedial**: Visibility of details should be unchanged form baseline	RhRh29, 72mAs: 98 Baseline: 99	Acceptable	-

Dose

Test	Reference	Limiting values	Result	Acceptable?	Comments
Dose to the standard breast	NHSBSP0604v3 3.6.1 EU2006 2.5.1	Perspex thickness / Remedial (NHSBSP), Acceptable (EU2006) / Achievable (EU2006) 2: 1.0 / <0.6 3: 1.5 / <1.0 4: 2.0 / <1.6 4.5: 2.5 / <2.0 5: 3.0 / <2.4 6: 4.5 / <3.6 7: 6.5 / <5.1	STD / CONT / DOSE 0.92 / **1.11** / 0.59 0.93 / 1.36 / 0.72 1.12 / 1.51 / 0.91 1.16 / 1.47 / 0.97 1.42 / 1.79 / 1.19 2.03 / 2.42 / 1.63 2.69 / 3.11 / 2.17	Acceptable	-

Summary of Results of Automatic CDMAM reading

physics ID	NGDT
Local ID / location	Room1
Centre	Nottingham
Digital make	GE
Digital model	Essential
Date	11 March 2014
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

unprocessed		
added px	4	cm
spacer	0	cm
mode	STD	
kV	29	
target	Rh	
filter	Rh	
mAs	72.5	
MGD	1.41	mGy

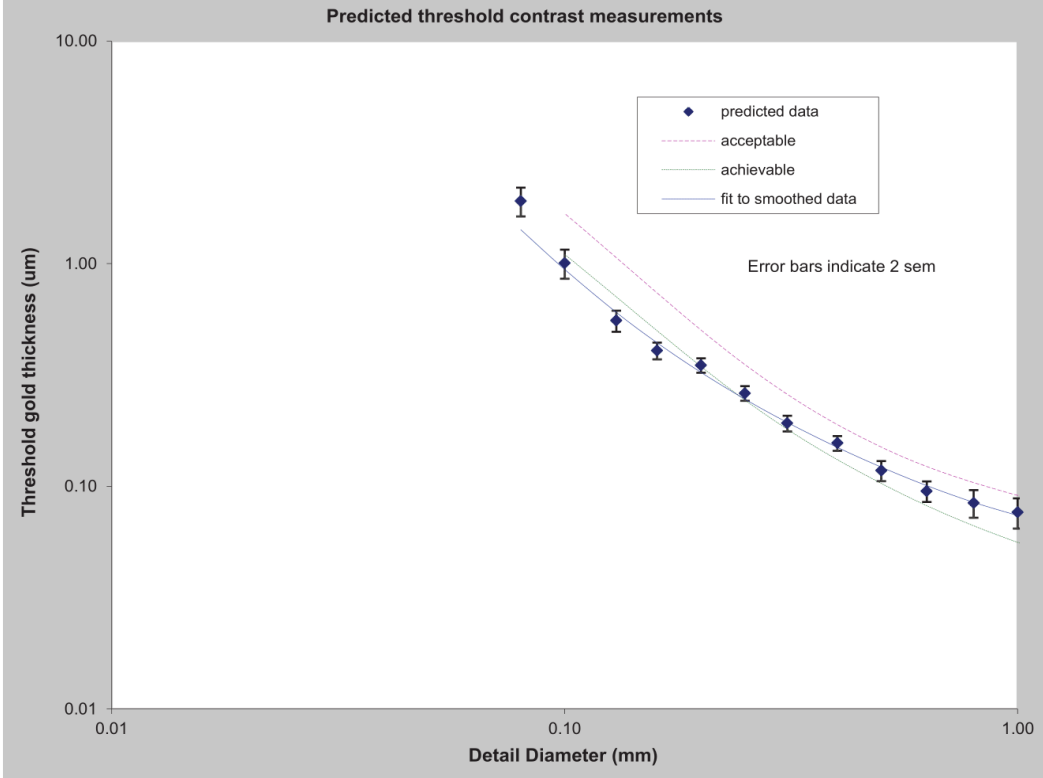
Comments: SN 1074

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.08**	**0.012**	**0.07**
0.80	0.08	0.012	0.08
0.63	0.10	0.010	0.10
0.50	**0.12**	**0.012**	**0.12**
0.40	0.16	0.012	0.15
0.31	0.19	0.015	0.19
0.25	**0.26**	**0.020**	**0.25**
0.20	0.35	0.026	0.32
0.16	0.41	0.035	0.44
0.13	0.55	0.060	0.60
0.10	**1.01**	**0.151**	**0.94**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.08**	**0.07**	**0.012**
0.5	0.15	0.103	**0.12**	**0.12**	**0.012**
0.25	0.352	0.244	**0.26**	**0.25**	**0.020**
0.1	1.68	1.1	**1.01**	**0.94**	**0.151**



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A1.6 Nottingham, 6-monthly routine tomosynthesis testing, March 2014

Region	East Midlands
NHSBSP programme	Notts
Screening Centre	Nottingham
Make of x-ray unit	GE
Model	Essential
Year installed	MTD installed 2013
Serial number (manf date) - generator:	628319BU6
Serial number (manf date) - tube:	133955TX5
Serial number (manf date) - detector:	628660BU3
	ADS 56.10
Software Version	Reconstruction Package
	VERSION RECON_01.10.1
Fixed / mobile	Fixed
Location	Room 1, NBI
Tested by	D. Whitwam & L. Toru
Date	**11 March 2014**
Reason for testing	**Routine Tomosynthesis 3D**
Physics ID for this system	NGDT
Local ID	Room 1

SUMMARY OF TEST RESULTS See following pages

COMMENTS & RECOMMENDATIONS

C1	**None**
Comment	
Reference	
Action required	
Deadline	

References

NHSBSP0604v3
Commissioning and routine testing of full field digital mammography systems, NHSBSP Equipment report 0604, Version 3, April 2009
EU2006
European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition, 2006
IPEM89
The commissioning and routine testing of mammographic x-ray systems, 2005 IPEM Report No89

Written by:
David Whitwam……..…….. ……..

Checked by:
V Jones ……..… ……..

Alignment

Test	Reference	Limiting values	Result					Acceptable?	Comments
Alignment of x-ray field to the light field	Draft NHSBSP TOMO protocol	**Remedial:** Misalignment >5mm along any edge		CWE	Nipple edge	Left	Right	Acceptable	-
			TF,24x30,-,Mo	0	0	-2	5		
			TF,24x30,-,Rh	0	0	-3	5		
			TF,18x24,C,Mo	-2	5	2	3		
			TF,18x24,C,Rh	-2	3	3	3		
Alignment of x-ray field to imaged field / detector	Draft NHSBSP TOMO protocol	**Remedial:** >5mm or <0mm overlap of image by x-ray field on all sides **Suspension:** >10mm overlap or >2mm unexposed border along CW edge with respect to image		CWE	Nipple edge	Left	Right	Acceptable	Acceptable within the limits of the measurment.
			TF,24x30,-,Mo	4	7	2	5		
			TF,24x30,-,Rh	3	7	0	5		
			TF,18x24,C,Mo	1	0	1	-2		
			TF,18x24,C,Rh	1	8	2	-2		
Alignment of reconstructed image volume to target volume	Draft NHSBSP TOMO protocol	**Remedial:** All markers at the top and bottom of the target volume should be brought into focus within the range of the reconstructed volume.						Acceptable	-

Detector Performance

Artefacts and dead pixel dropout	Draft NHSBSP TOMO protocol	See manufacturer's spec	Artefacts?					-
Detector resolution: Limiting spatial resolution	Draft NHSBSP TOMO protocol	Limiting spatial resolution <75% of commissioning value	3.15 x 3.55 lp/mm	Baseline:		3.55 lp/mm	Acceptable	-
Geometric Distortion and Artefact Spread	Draft NHSBSP TOMO protocol	Height of best focus	Nominal Height	12.5	32.5	52.5	Acceptable	-
			Average Slice	29	69	110.0		
			Max deviation from average	0.6	1.25	1.0		
		Positional accuracy	Max X Difference from mean (mm)	4.2	4.1	4.1		
			Max Y difference from mean (mm)	2.8	2.4	2.5		
		Artefact Spread	X Artefact Spread	0.5	0.5	0.5		
			Y Artefact Spread	0.3	0.3	0.3		
			Z resolution	6.23	6.07	5.89		

AEC

AEC repeatability	Draft NHSBSP TOMO protocol	**Remedial**: Max dev in mAs from mean: >5% **Suspension**: Max dev in mAs from mean: >10%	Max deviation =		3%			Acceptable	-
AEC performance - Automatic mode	Draft NHSBSP TOMO protocol	CNR: ±10% baseline	Auto 3D Slices	Perspex thickness	TFkV, mAs	CNR	%baseline	Acceptable	-
				2	MoMo26, 44	7.2	-1%		
				3	RhRh29, 38	4.6	-		
				4	RhRh29, 56	3.9	-		
				4.5	RhRh29, 62	3.8	-1%		
				5	RhRh29, 72	3.5	-		
				6	RhRh31, 89	3.5	-		
				7	RhRh31, 142	3.5	-3%		
		CNR: ±10% baseline	Auto 3D Slabs	Perspex thickness	TFkV, mAs	CNR	%baseline	Acceptable	
				2	,	6.4	-8%		
				3	,	4.0	-		
				4	,	3.6	-		
				4.5	,	3.3	-5%		
				5	,	3.2	-		
				6	,	3.2	-		
				7	,	3.2	-3%		

Image Quality

Test	Reference	Limiting values	Result	Acceptable?	Comments
Threshold contrast visibility - CDMAM	Draft NHSBSP TOMO protocol	Threshold gold thickness Detail diameter / acceptable / achievable 2 / 0.069 / 0.038 1 / 0.091 / 0.056 0.5 / 0.15 / 0.103 0.25 / 0.352 / 0.244 0.1 / 1.68 / 1.10	Fit to predicted gold thickness RhRh29, 76mAs, 1.46mGy n/a 0.08 0.12 0.25 1.28	Acceptable	-
Regular IQ tests - TORMAX	Draft NHSBSP TOMO protocol	**Remedial**: No of details detected should meet NHSBSP standards for film-screen systems & be unchanged from baseline Target / Min std / Remedial / Suspension 6mm / <0.8% / <1.2% / <1.4% 0.5mm / <3% / <5% / <8% 0.25mm / <5% / <8% / <11%	MoMo28, 100mAs 0.5% 3% 5%	Acceptable	-
Regular IQ tests - TORMAM	Draft NHSBSP TOMO protocol	**Remedial**: Visibility of details should be unchanged form baseline	RhRh29, 76mAs / Baseline 84 / 87	Acceptable	-

Dose

Test	Reference	Limiting values	Result	Acceptable?	Comments
Dose to the standard breast	Draft NHSBSP TOMO protocol	Perspex thickness / Remedial (NHSBSP), Acceptable (EU2006) / Achievable (EU2006) 2 / 1.0 / <0.6 3 / 1.5 / <1.0 4 / 2.0 / <1.6 4.5 / 2.5 / <2.0 5 / 3.0 / <2.4 6 / 4.5 / <3.6 7 / 6.5 / <5.1	Auto 3D Slices / Auto 3D Slabs / - **1.18** / - / - 1.06 / - / - 1.27 / - / - 1.29 / - / - 1.38 / - / - 1.94 / - / - 2.69 / - / -	Acceptable	-

Summary of Results of Automatic CDMAM reading

physics ID	NGDT1403
Local ID / location	Room 1
Centre	Nottingham
Digital make	GE
Digital model	Essential Tomo
Date	11 March 2014
manufacturer of X-ray set	
model of X-ray set	
model of CR plate	

unprocessed		
added px	4	cm
spacer	0	cm
mode	Auto 3D	
kV	29	
target	Rh	
filter	Rh	
mAs	76.1	
MGD	1.46	mGy

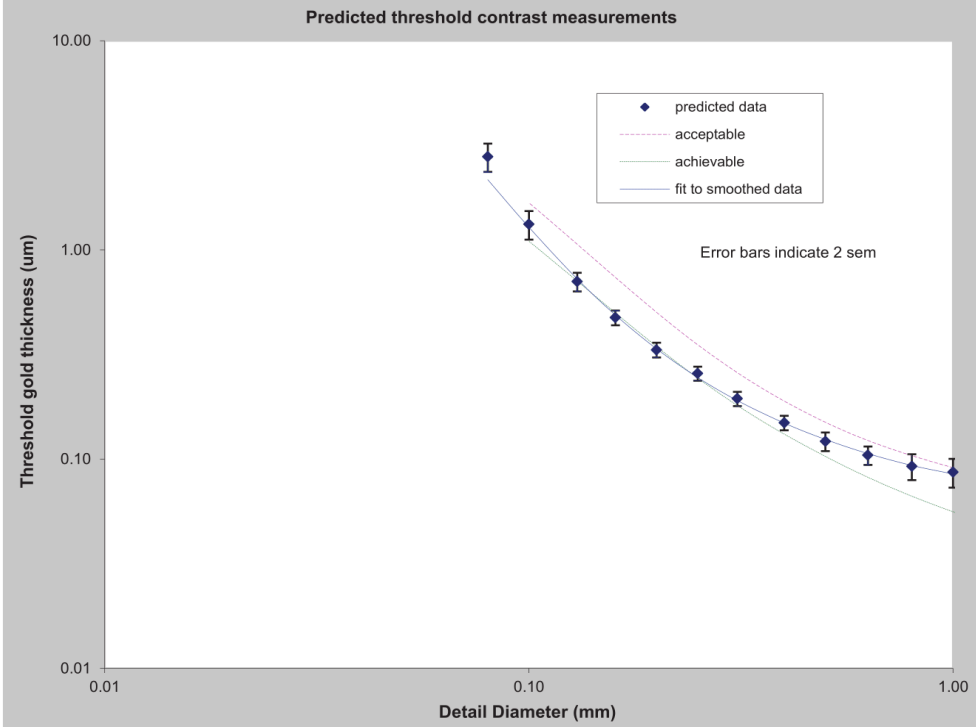
Comments: SN 1074

Predicted CD curve for human observer

Diameter (mm)	threshold gold thickness	2 sem	fitted curve
1.00	**0.09**	**0.014**	**0.08**
0.80	0.09	0.013	0.09
0.63	0.10	0.011	0.11
0.50	**0.12**	**0.012**	**0.12**
0.40	0.15	0.012	0.15
0.31	0.19	0.015	0.19
0.25	**0.26**	**0.020**	**0.25**
0.20	0.33	0.027	0.34
0.16	0.47	0.039	0.49
0.13	0.70	0.073	0.73
0.10	**1.32**	**0.205**	**1.28**

Limits in protocol

	Threshold gold thickness		predicted gold thickness	fit to predicted gold thickness	2 sem for fitted value
diameter	acceptable	achievable			
2	0.069	0.038	n/a	n/a	n/a
1	0.091	0.056	**0.09**	**0.08**	**0.014**
0.5	0.15	0.103	**0.12**	**0.12**	**0.012**
0.25	0.352	0.244	**0.26**	**0.25**	**0.020**
0.1	1.68	1.1	**1.32**	**1.28**	**0.205**



\\srv-mps-001\xls_mamo\SURVEY\DATA\EAST_MID\NOTTINGHAM\NGDT Essential with Tomosynthesis Room 1\NGDT1403\CDMAM slice 47.xls 04/09/2015

Appendix 2: Dose surveys

A2.1 Survey summary for Derby

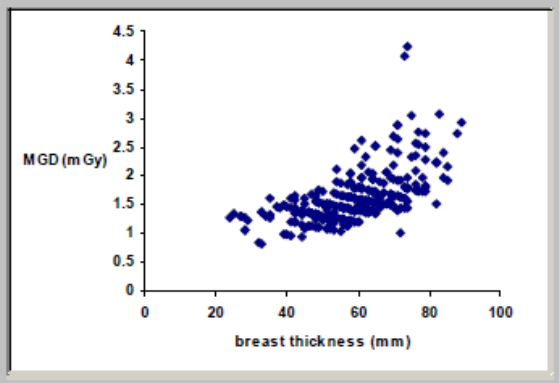
NHSBSP Breast Dose Survey

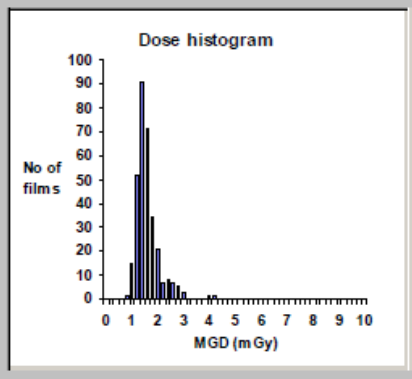
Survey No:	1
Centre:	Derby
Date of first exam:	
Date of last exam:	
X-ray make:	GE
Model:	SenoClaire
Local id:	DBSE
Installation:	fixed
kV mode:	auto
standard kV:	0
Routine/age trial:	

Tomo mode: Tomo

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	Auto	MGD mAs:	59.0
kV set:	28	HVL:	0.430
target:	Rh	MGD:	1.40
filter:	Rh		





Count of images

view	main films	Extra films
CC	158	
OB	160	

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	158	0.83	4.07	1.52	57
OB	160	0.84	4.25	1.68	59

Average doses per examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	1	0.66	0.66	0.66
Two view	159	0.67	4.16	1.59

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	47	1.50	0.08	55

Summary of X-ray factors selected

Anode	Filter	kV	films
Mo	Mo	26	1
Mo	Rh	26	7
Mo	Rh	27	1
Rh	Rh	29	260
Rh	Rh	30	3
Rh	Rh	31	47

A2.2 Survey summary for Nottingham

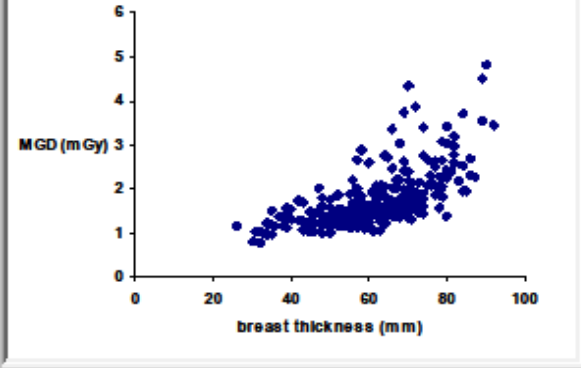
NHSBSP Breast Dose Survey

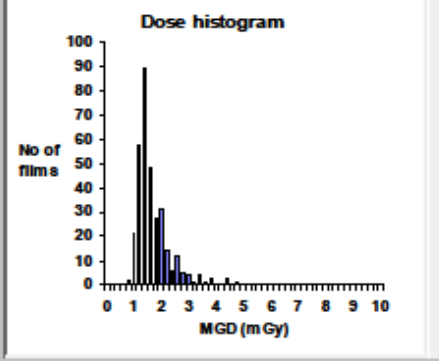
Survey No:	2
Centre:	Nottingham
Date of first exam:	19/02/2014
Date of last exam:	
X-ray make:	GE
Model:	SenoClaire
Local Id:	NGDT
Installation:	fixed
kV mode:	auto
standard kV:	
Routine/age trial:	mixed

Tomo mode: Tomo

MGD to standard breast

auto/manual kV:	auto	PMMA thickness:	45mm
auto/AEC setting:	Auto	MGD mAs:	62.0
kV set:	29	HVL:	0.420
target:	Rh	MGD:	1.30
filter:	Rh		





Count of images

view	main films	Extra films
CC	162	6
OB	158	4

Summary of X-ray factors selected

Anode	Filter	kV	films
Mo	Rh	26	1
Mo	Rh	29	2
Rh	Rh	27	1
Rh	Rh	29	236
Rh	Rh	31	92

Average doses for main images

view	No of films	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)	mean thickness (mm)
CC	162	0.76	4.48	1.60	60
OB	158	0.79	4.81	1.77	61

Average doses per examination

	No of women	min MGD (mGy)	max MGD (mGy)	mean MGD (mGy)
One view	4	0.57	3.23	1.45
Two view	158	0.88	4.12	1.73

Average dose for 50-60mm thick breasts

View	No of films	mean MGD (mGy)	2 s.e.m.	mean thickness (mm)
OB	39	1.51	0.10	56

Appendix 3: Further GE QC tests

A3.1 Weekly flat field 3D test

This test checks the flatness and homogeneity of the reconstructed flat field planes. “Flat field” is selected from the 3D tests in the QAP menu. A tomosynthesis exposure is made using a 25mm thick acrylic Perspex block attenuator, covering the whole image receptor. The compression paddle is not used. Exposure parameters are set automatically by the system – large focus, 26kV Mo / Mo, 40mAs.

At the end of the tomosynthesis exposure the Brightness non-uniformity and SNR non-uniformity results are displayed at the AWS. The non-uniformity corresponds to the difference between the maximum and the minimum of the pixel value or SNR divided by the average.

The results were generally below the GE upper limit as shown in Figures A3.1 to A3.4. The high values for Brightness non-uniformity at Nottingham during February and March 2014 were referred to GE. After a software upgrade the results became acceptable.

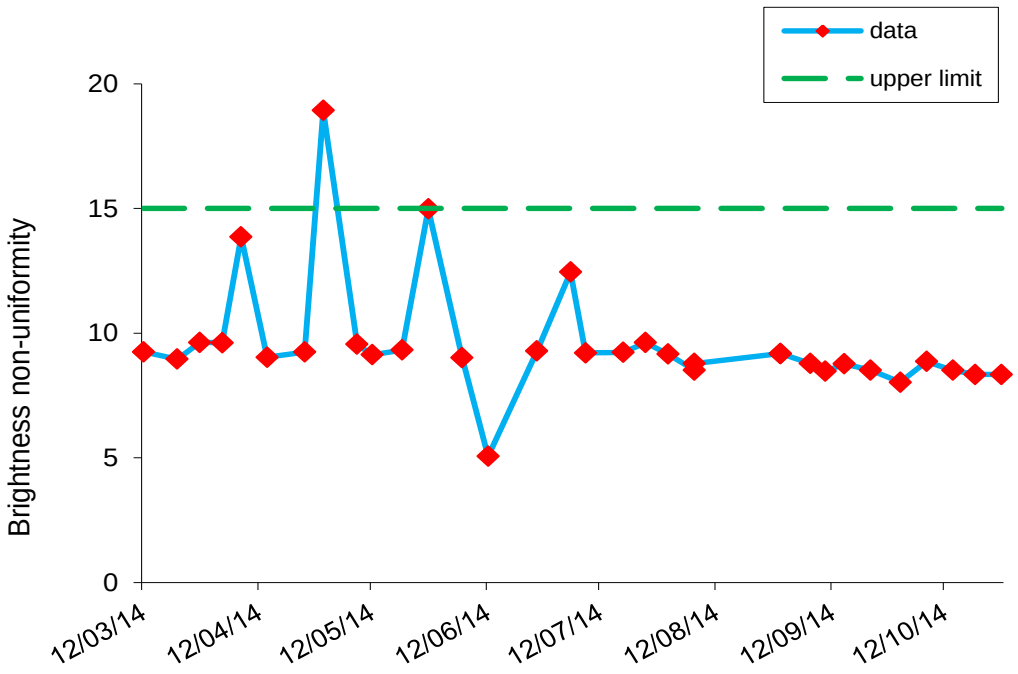


Figure A3.1. GE QAP flat field 3D test: Brightness non-uniformity for Derby

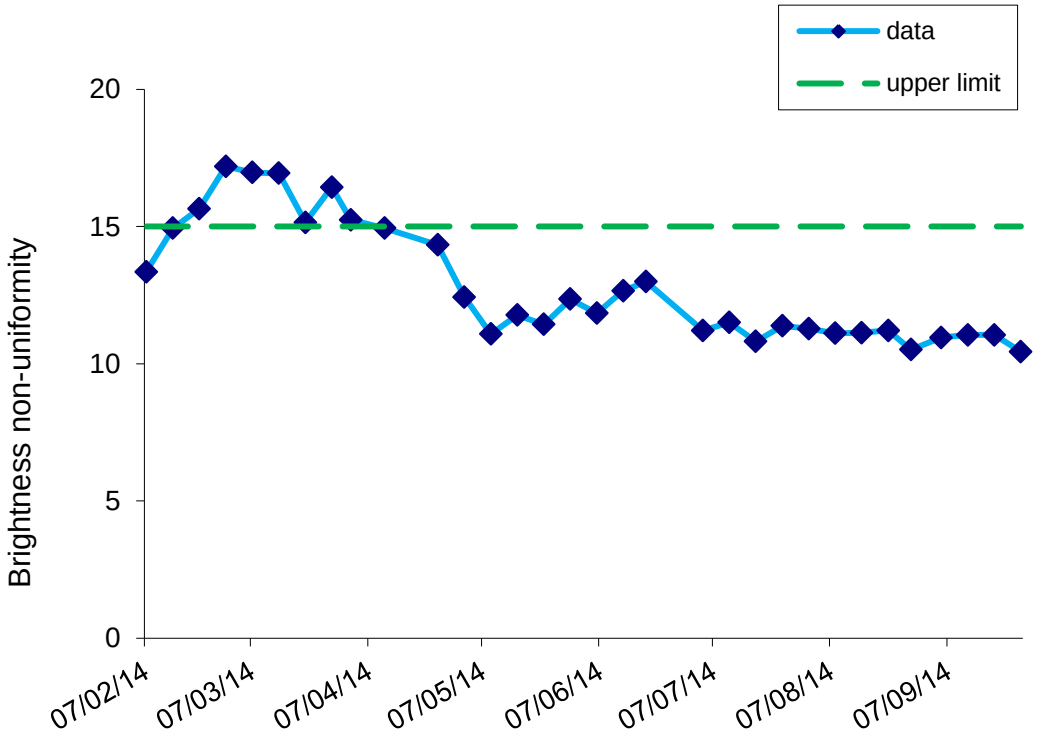


Figure A3.2. GE QAP flat field 3D test: Brightness non-uniformity for Nottingham

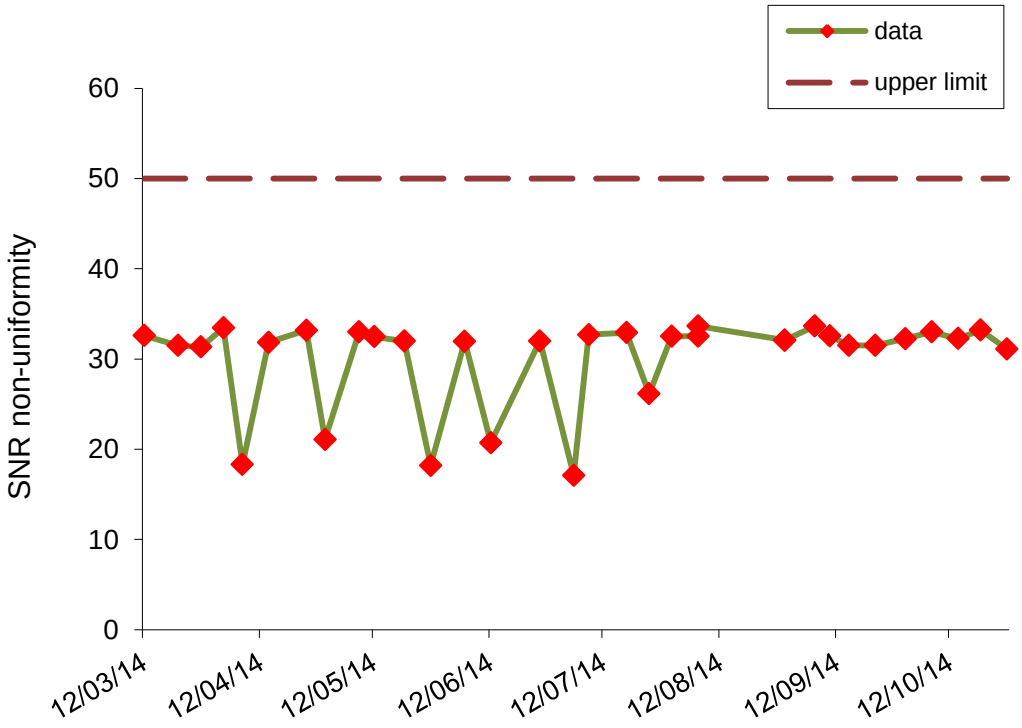


Figure A3.3. GE QAP Flat field 3D test: SNR non-uniformity for Derby

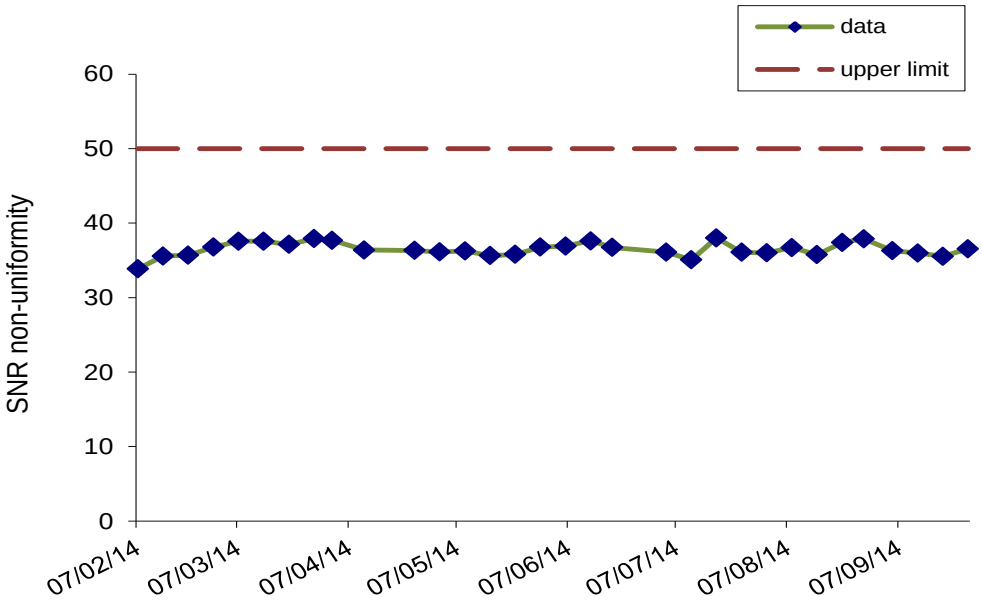


Figure A3.4. GE QAP flat field 3D test: SNR non-uniformity for Nottingham

A3.2 Weekly MTF measurement with MTD (2D)

This test is described in Section 3.3.1.1, and the results include both CNR and MTF. The MTF results are a check that contrast is adequate over the 0-5 lp/mm spatial frequency range. The MTF values at 2 lp/mm and 4 lp/mm are shown in Figures A3.5 to A3.12.

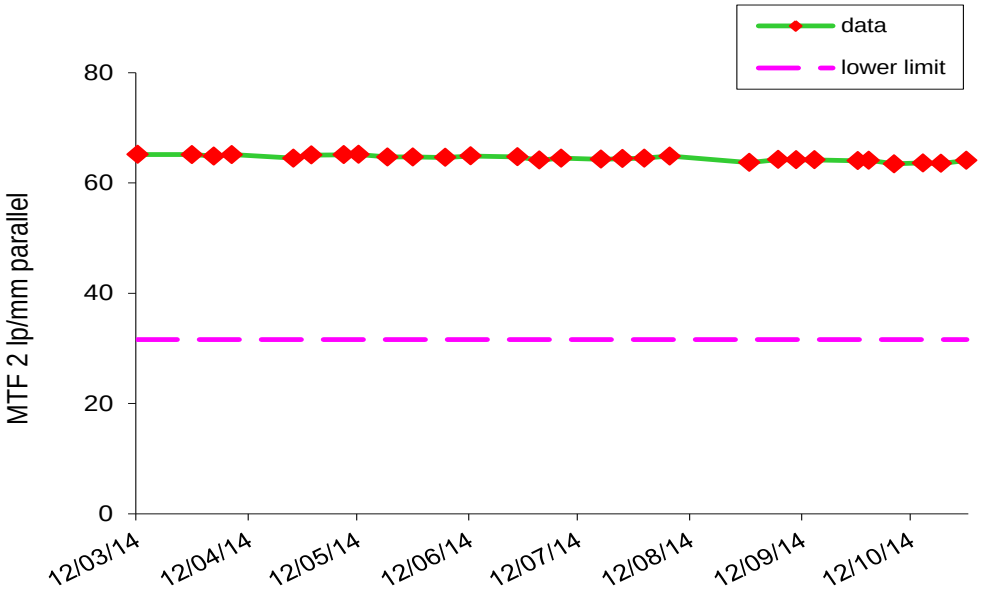


Figure A3.5. GE QAP weekly MTF with MTD, 2 lp/mm parallel for Derby

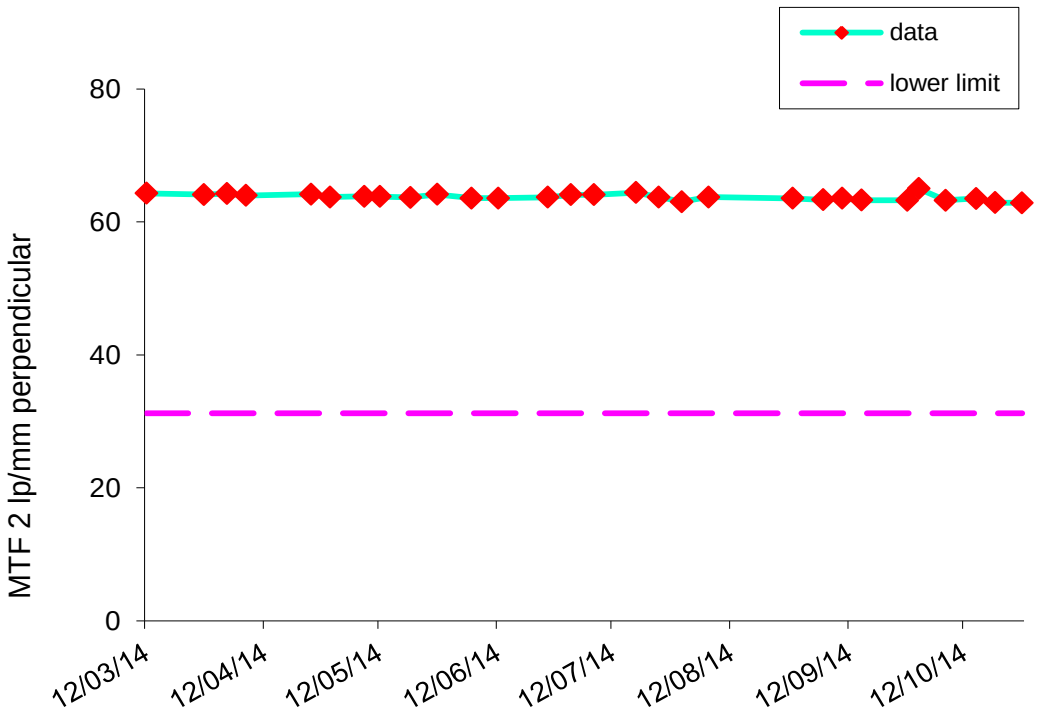


Figure A3.6. GE QAP weekly MTF with MTD, 2 lp/mm perpendicular for Derby

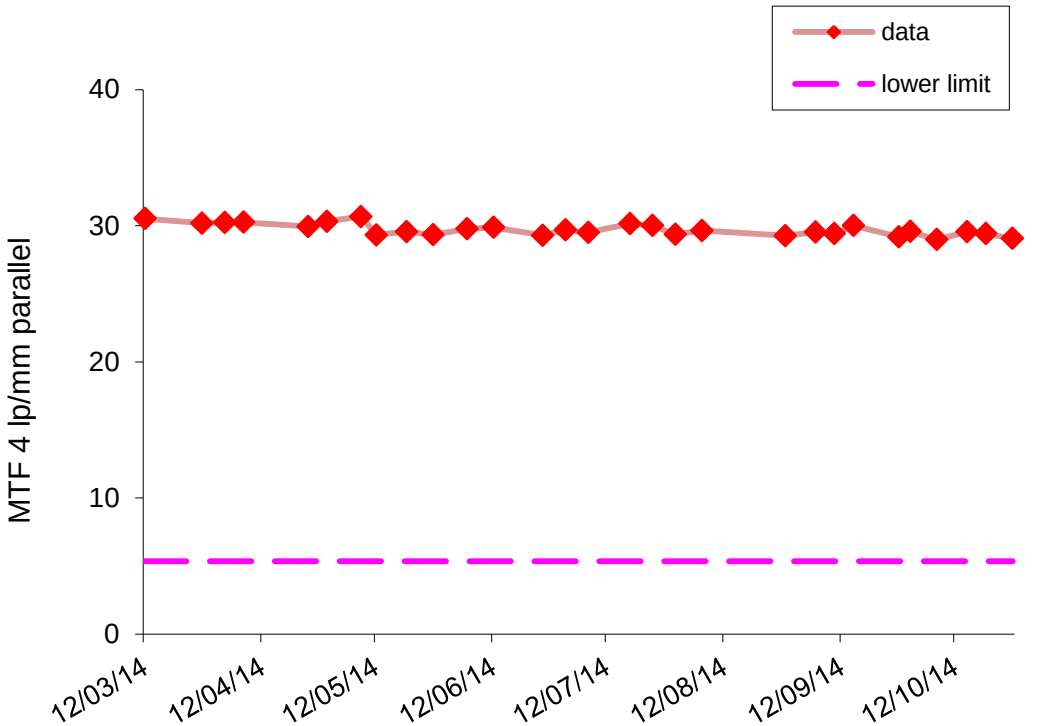


Figure A3.7. GE QAP weekly MTF with MTD, 4 lp/mm parallel for Derby

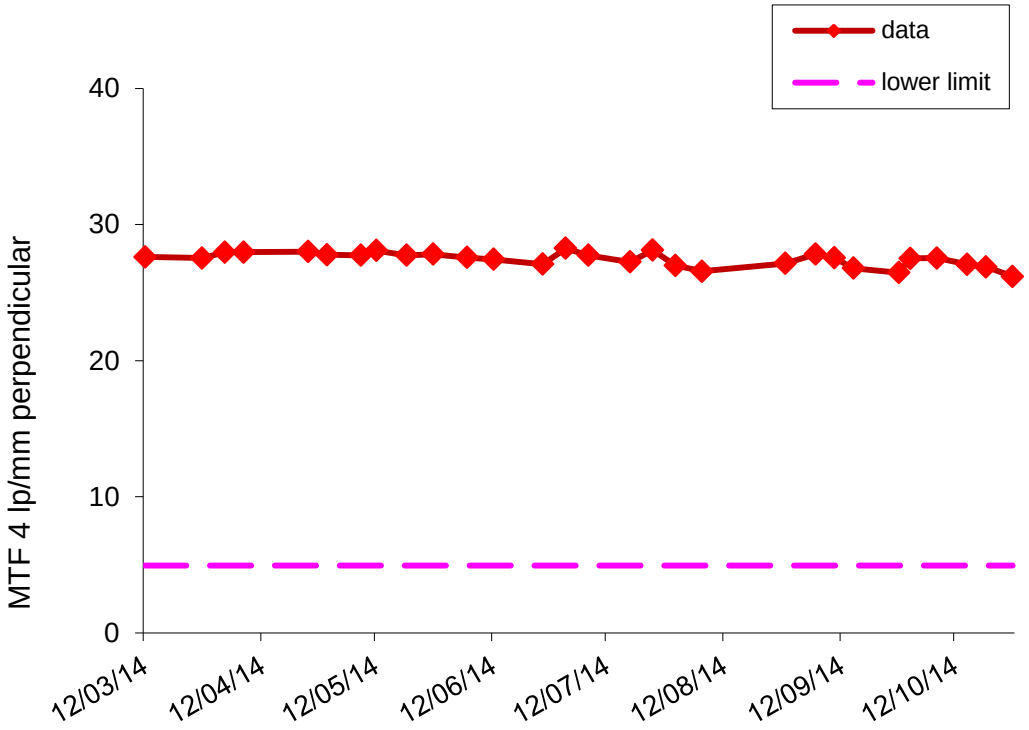


Figure A3.8. GE QAP weekly MTF with MTD, 4 lp/mm perpendicular for Derby

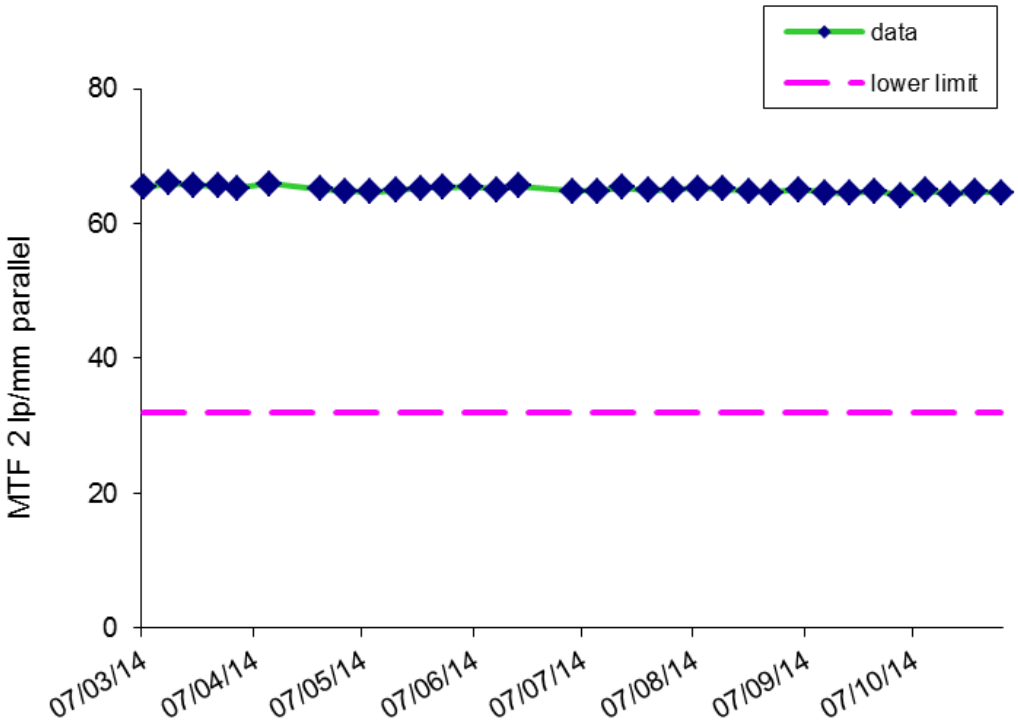


Figure A3.9. GE QAP weekly MTF with MTD, 2 lp/mm parallel for Nottingham

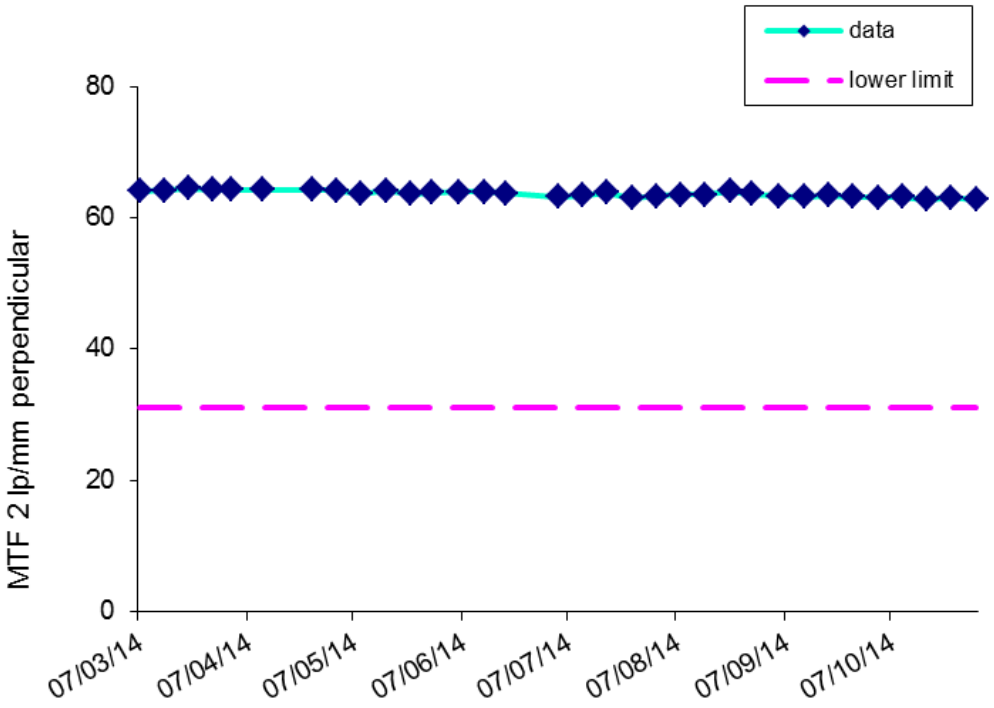


Figure A3.10. GE QAP weekly MTF with MTD, 2 lp/mm perpendicular for Nottingham

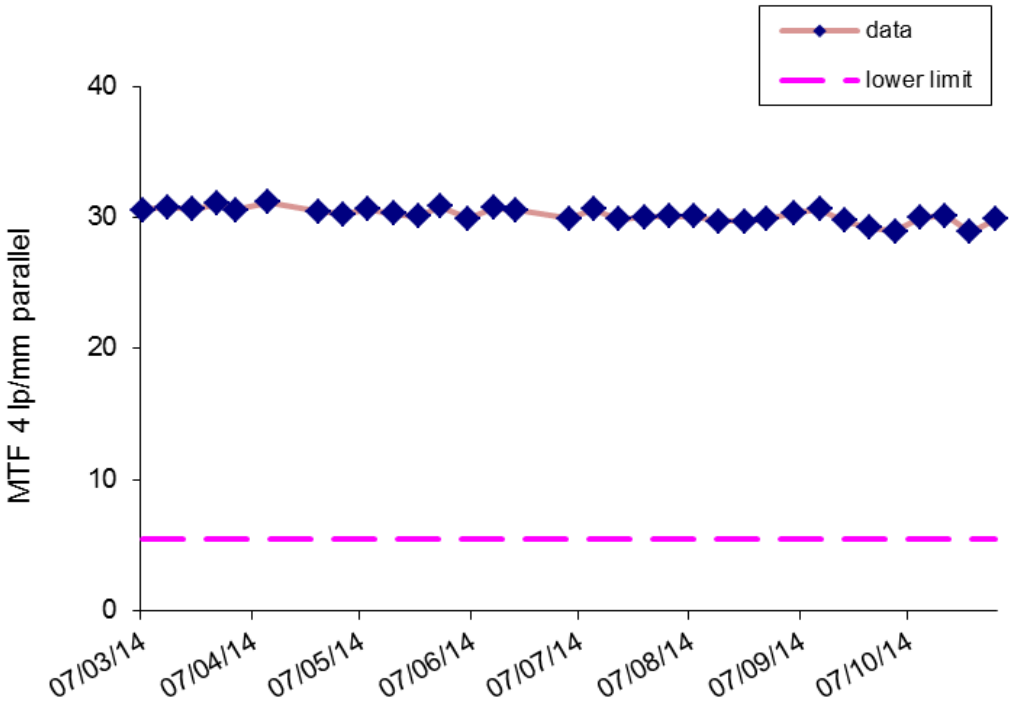


Figure A3.11. GE QAP weekly MTF with MTD, 4 lp/mm parallel for Nottingham

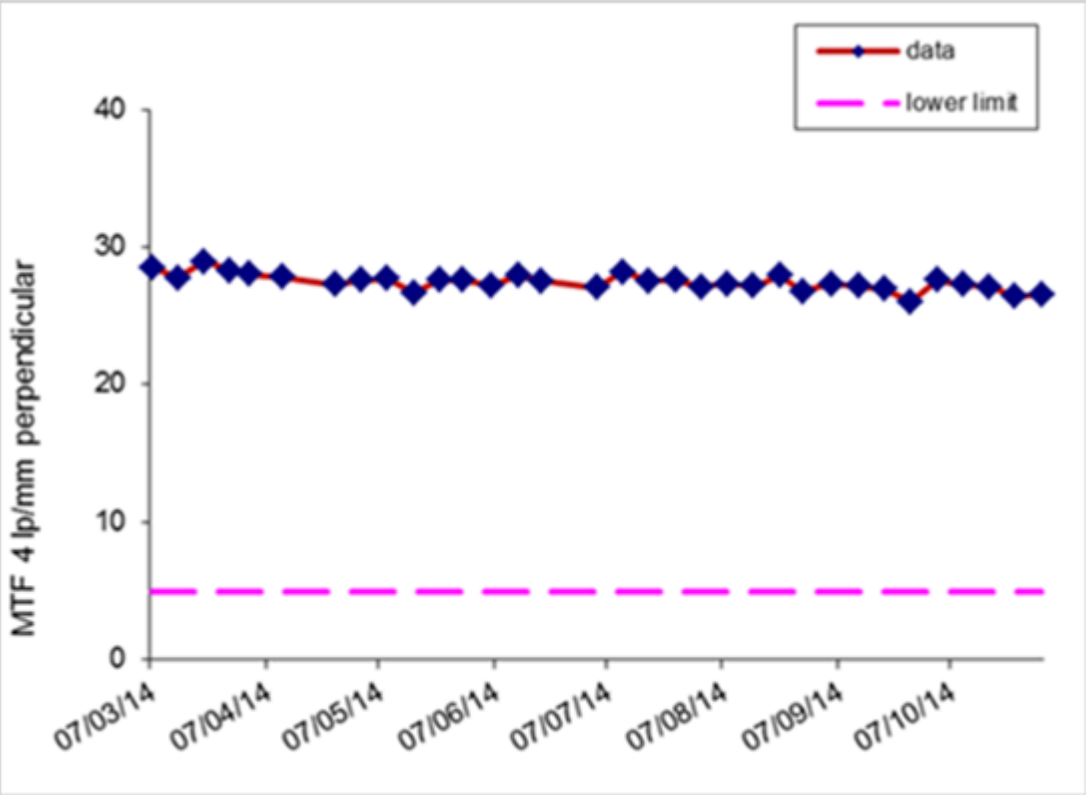


Figure A3.12. GE QAP weekly MTF with MTD, 4 lp/mm perpendicular for Nottingham

A.3.3 Monthly grid texture test

This test measures the amount of grid texture in 2D images. Grid texture appears in images when the positioning of the MTD is different from the positioning used in the gain calibration.

Using the flat field test object (25mm thick acrylic) 10 exposures are made at 26 kV Mo / Mo with mAs values increasing from 5 to 400. Results are displayed for the texture level with Pass/Fail status.

The QC tests continued after the evaluation period. The upward trend shown in Figure A3.14 for grid texture at Nottingham continued and exceeded the upper limit in November 2014. GE were informed and the system was recalibrated which resolved the problem.

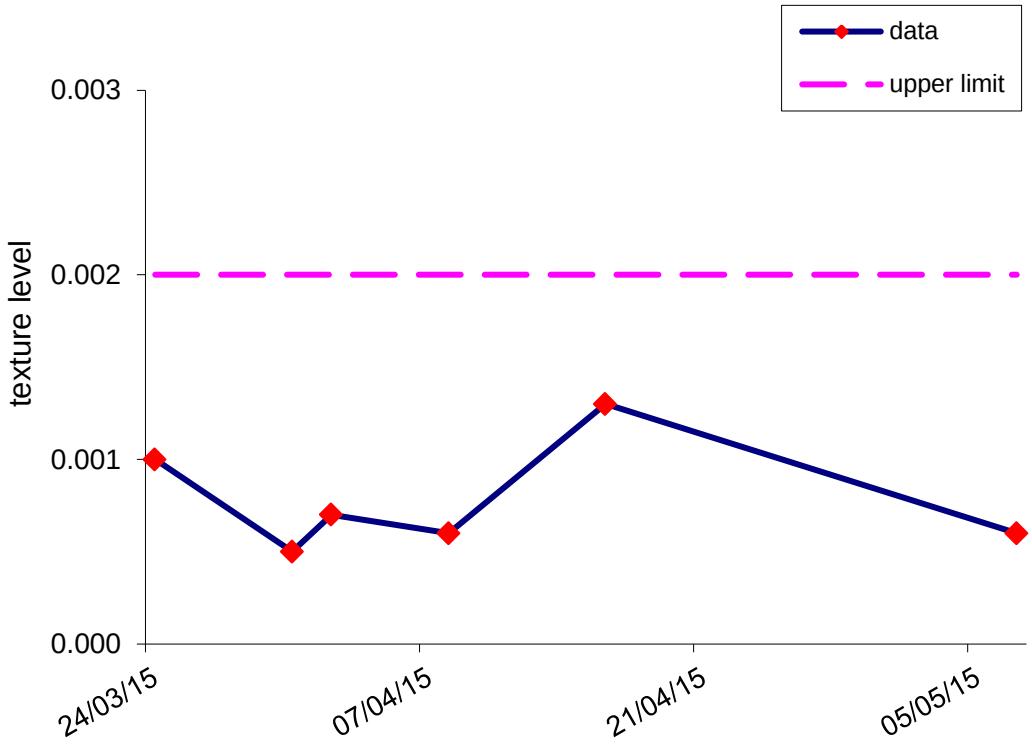


Figure A3.13. GE QAP monthly grid texture test for Derby

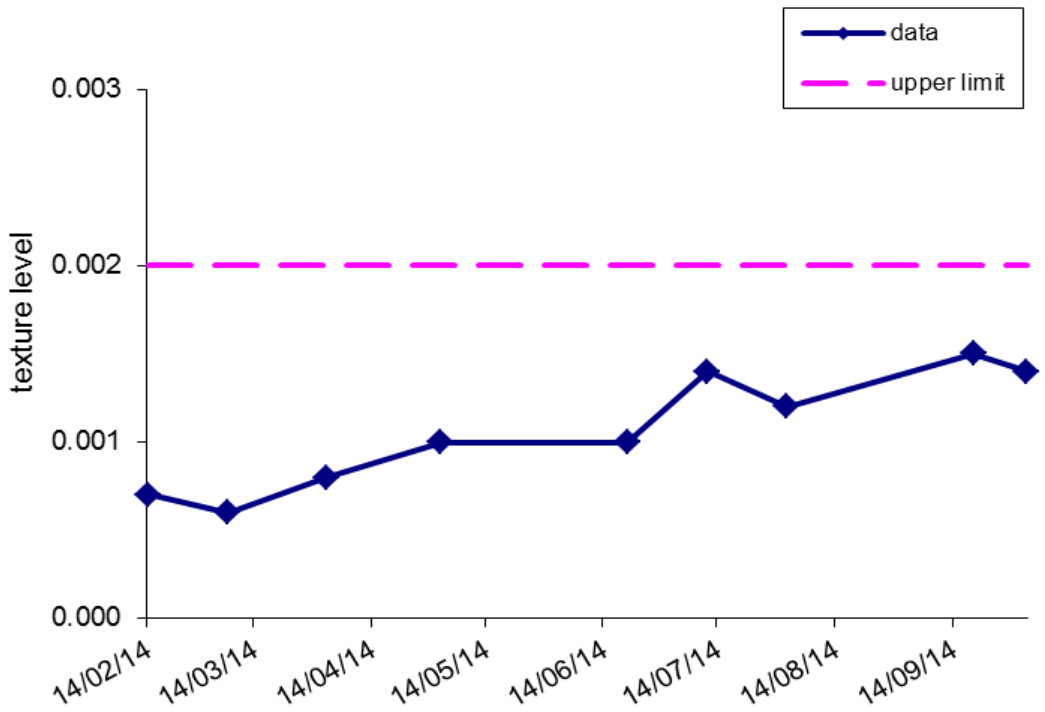


Figure A3.14. GE QAP monthly grid texture test for Nottingham

Appendix 4: Fault reports requiring engineer visits

Table A4.1 Faults reported at Nottingham

Date	Fault	Solution
17/04/14	SNR slightly raised - detector very warm – error codes connecting	Wait for detector to cool
11/06/14	Tomosynthesis attachment not accepted by unit	Engineer straightened bent pin on tomosynthesis connector plug

Appendix 5: Radiographers' answers to questionnaire

	Comments and observations	Comparison to 2D
How do you rate the supplier's operation manual (if used)?	5 good, 6 not seen We were late getting the manual, two weeks following the applications training	5 same, 6 N/A
How good was the clinical in house training for tomosynthesis provided by the supplier for:		
a. Modality?	1 excellent, 8 good, 2 average A bit rushed never got shown any QA, ran out of time.	11 same
b. Acquisition workstation?	1 excellent, 4 good, 3 average, 3 satisfactory Not shown how to reconstruct images from PACS.	11 same
How do you rate the units ease of use for tomosynthesis?	10 good , 1 average	
How easy was it to attach / remove the tomosynthesis device?	1 excellent, 4 good, 2 average, 2 satisfactory, 2 poor Too heavy to carry Very difficult and bulky Once the cart was delivered, one poor became excellent	

How do you find carrying out the:		
Special QC test for tomosynthesis?	1 difficult, 9 average, 1 easy Not shown QA Ran out of time on training day	
Calibration test for tomosynthesis?	9 average, 1 easy, 1 not aware	
Reporting station QC?	4 average, 7 not aware	
Were the compression times acceptable for each exposure?	10 yes, 1 no comment No feedback from ladies	5 same, 5 worse
Did the unit performance limit the patient throughput?	4 yes, 7 no	7 same, 4 worse
How do you rate the comfort level during tomosynthesis exposures, including acceptance of gantry motion?	6 good, 4 average, 1 satisfactory Position of head can be difficult Some women are finding the longer exposures difficult to be in the oblique position for long Similar to 2D Need to ensure woman holds on to correct handle for oblique Always informed woman that the gantry face panel moved	
Range of controls and indicators (on-screen icons) for tomosynthesis:		
a. Were all the expected controls present?	10 yes, 1 no comment	10 same, 1 no comment

b. Were they easy to find?	10 yes, 1 no comment	10 same, 1 no comment
c. Were the icons easy to use?	10 yes, 1 no comment	10 same, 1 no comment
How do you rate the time for:		
a. An image to appear at the acquisition workstation?	2 excellent, 3 good, 2 average, 4 satisfactory	6 same, 5 worse, 4 no comment
b. Storage of the image?	1 excellent, 3 good, 4 average, 2 satisfactory, 1 poor	
	Slower than 2D A bit longer than 2D A long time, depends on traffic on PACS Lots of waiting Only store snap shots and raw data	
How do you rate the image handling at the acquisition workstation:		
a. Scrolling through the image levels?	5 good, 3 average, 1 poor, 2 not used	
b. The processing facilities?	4 good, 4 average, 1 poor, 2 not used	
c. Use the query / retrieve?	4 good, 2 average, 3 satisfactory, 2 not used	
	Slow to retrieve Slow within a busy clinic	
How easy was it to use, for tomosynthesis, the following:		
a. Keyboard?	1 excellent , 3 good, 5 average, 1 satisfactory, 1 poor	8 same, 3 no comment

	8 good, 1 satisfactory, 2 not used	
b. Scrolling wheel?	Good for fine control	
How do you rate the following:		
a. Image quality at the acquisition work station?	3 good, 5 average, 2 satisfactory, 1 poor Very grainy image cuts off at bottom of the image Seems reasonable don't have any other to compare with	
b. Overall image quality in tomosynthesis mode?	2 good, 5 average, 3 satisfactory, 1 poor Images can appear grainy, very grainy, not sharp and pixels apparent	
What was your level of confidence in the unit?	1 excellent, 7 good, 3 satisfactory	1 better, 7 same, 1 worse, 2 no comment
Were there any potential hazards with use:		
a. To you?	8 no, 3 yes	8 same, 3 worse
b. The woman?	8 no, 3 yes	8 same, 3 worse

Additional comments on general or imaging performance in tomosynthesis mode	Very easy to use Only referred to the operators' manual once in order to set exposure for very thin breasts, clear to use and produce comparable results to automatic exposure Compression paddle does not lift as high as standard equipment, so less space vertically

Appendix 6: Radiologists' answers to questionnaire

	Comments and observations
How good were the operator manual instructions for tomosynthesis?	1 good, 2 not used, 1 unaware, 2 no comment
How good was the application training for tomosynthesis provided by the supplier?	1 excellent , 3 good, 1 average, 1 satisfactory, 1 poor
Did you attend any external training courses? If so where?	5 Kings College, London 2 Buc, Paris
How do you rate the use of the reporting workstation controls?	
a. Mouse/tracker ball	1 excellent, 4 good, 1 average, 1 satisfactory
b. Keyboard	1 excellent, 4 good, 1 average, 1 satisfactory
c. Keypad	2 excellent, 3 good, 1 average, 1 satisfactory
How do you rate the image handling tools?	2 excellent, 1 good, 3 average, 1 poor Accessing the image manipulation tools is poor and difficult. These are not intuitive Slow and unresponsive
How do you rate the special tomosynthesis image handling tools?	2 excellent, 1 good, 2 average, 2 satisfactory

How do you rate the visibility and usability of on-screen icons?	2 excellent,1 good, 2 average, 1 satisfactory, 1 poor I find the measuring tool difficult The IDI workstation is not very intuitive, you either need to be shown how to do everything or spend a lot of time searching through the online help
Did you sometimes change the slab thickness when reviewing the images?	7 N/A
How do you rate the reading / reporting flow pattern in tomosynthesis?	4 good,1 satisfactory, 1 not used, 1 only used for assessment clinics
How do you rate the time for an image to appear on the screen in tomosynthesis mode?	
a. New patient selection	4 good, 1 average, 2 satisfactory It feels like a long time when waiting to view a newly acquired tomosynthesis image Not easy to get to next client Annoying “you have not viewed all the images” message
b. In-examination change	6 good, 1 satisfactory
How easy was it to record findings for tomosynthesis on NBSS?	1 easy, 4 N/A No method of recording tomosynthesis findings, just a box to tick if additional images have been taken Not recorded separately, part of the image mammogram record
How easy is it to adjust the height and angle of the recording monitors to suit the user?	1 average, 2 N/A, 1 not needed, 3 not tried

How easy was it to navigate between the tomosynthesis slices?	5 easy, 2 average
How easy was it to set up different hanging protocols in tomosynthesis? How easy was it to change from one hanging protocol to another in tomosynthesis?	1 easy, 2 difficult, 1 not necessary Hanging protocols generally left as they were Easy to change from one to another, it i the changing of the protocols themselves that is difficult
What is your opinion on the following on the whole image quality provided by the tomosynthesis system:	
a. Contrast	1 excellent, 5 good,1 average
b. Sharpness	1 excellent, 5 good, 1 average Synthetic 2D images seem poor; often cancers seen on conventional 2D images are not visible on synthetic
What is your overall level of satisfaction with using this tomosynthesis system for assessment?	1 excellent, 5 good, 1 average
Additional comments on general or imaging performance of the system for tomosynthesis	No significant problems Tomosynthesis is a useful technique I think that it is very helpful in assessment clinic for assessment of distortions The delivery of the image quality and ease of use of IDI workstation is poor The 2D synthetic views need future evaluation

Appendix 7: Manufacturer's comments

The manufacturer has added the following comments that are not part of the current evaluation, but provide further information about the equipment

- With reference to the slight reduction in space between the detector and the compression plate when positioning large breasts (Section 4.9) - to compensate for the reduced space, an "elevated paddle" is provided to extend the range. This can be used for most breasts except the thinnest.

- With reference to parts of the projection images being cut off (Sections 7.12 and 7.16) - this is not a problem, but is the consequence of the angulation of the tubes changing from projection to projection. The reconstructed tomosynthesis volume is actually wider than a usual 2D view, but not all the volume can be reconstructed from all projections. The extreme bands in the tomosynthesis planes in the direction of the sweep are reconstructed from a reduced number of projections.

- With reference to setting manual exposures for women with smaller breasts (Section 7.16) - this statement does not reflect reality. The AOP performs for all breast thicknesses, starting with the thinnest. As stated in the manual, the AOP is verified to be optimized for compressed breast thicknesses in the range 20mm to 80mm. However, it operates for thinner breasts with acceptable results. This is the same as in 2D.